AD________________

Award Number: DAMD17-94-C-4127

TITLE: Real Time 3D Ultrasound for Physiological Monitoring 22258

PRINCIPAL INVESTIGATOR: Richard J. Littlefield, M.S.

CONTRACTING ORGANIZATION: Battelle Pacific Northwest Laboratory
Richland, Washington 99352

REPORT DATE: September 2000

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
Distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	September 2000	Final (15 Sep 94 – 14 Aug 00)

4. TITLE AND SUBTITLE
Real-Time 3D Ultrasound for Physiological Monitoring 22258

5. FUNDING NUMBERS
DAMD17-94-C-4127

6. AUTHOR(S)
Richard J. Littlefield

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Battelle Pacific Northwest Laboratory
Richland, Washington 99352

E-MAIL: Rik.Littlefield@pnl.gov

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 Words)***

This project was funded to develop a field prototype medical imaging system utilizing 3-D ultrasound. Initial research focused on development of advanced sensor technology utilizing a dense 2-D array transducer with electronic scanning, unfocused spherical wavefront transmission, and computational reconstruction (focusing) based on Fourier Transform holography, with the goal of acquiring high quality 3-D images in real time. Valuable theoretical results were obtained, but experimental evidence indicated that a usable system would be impractical to construct using available fabrication technology. The research effort then refocused on development of a series of fully functional prototype systems utilizing conventional 1-D array transducers combined with mechanical scanning to acquire 3-D snapshots over a period of several seconds. These systems, called MUSTPAC (Medical UltraSound, Three dimensional, Portable, with Advanced Communication), were used to investigate and demonstrate the utility of 3-D ultrasound as a telemedicine tool for use by non-specialist operators. The MUSTPAC-1 system was field-tested in Bosnia and Germany in August 1996 and achieved international recognition in 1997 (Discover Award). Further development and technology transfer resulted in the MUSTPAC-3 freehand scan system, based on now off-the-shelf hardware and software. The MUSTPAC-3 is currently undergoing clinical evaluation under new non-DARPA programmatic funding.

14. SUBJECT TERMS
Real-Time 3D Ultrasound, Physiological Monitoring, Telemedicine

15. NUMBER OF PAGES
140

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

TABLE OF CONTENTS

1. INTRODUCTION

The goal of this project was to develop a field prototype medical imaging system utilizing 3-D volumetric ultrasound. This goal was realized with development of the MUSTPAC™ (Medical UltraSound, Three-dimensional, Portable, with Advanced Communications). MUSTPAC™ is an ultrasound telemedicine system that allows a patient to be scanned at any convenient location by an operator with limited training and no ultrasound diagnostic skills, then have those scans analyzed by a diagnostic expert at a center of excellence at any location. This technology may have widespread application in both military healthcare and civilian rural and emergency healthcare, resulting in both improved quality of care and reduced costs.

2. BODY

2.1. BACKGROUND

Inexpensive, portable diagnostic imaging systems can play a key role in decreasing battlefield fatalities and reducing the cost of military health care. Ultrasound imaging is a particularly promising modality because it does not use ionizing radiation (unlike X-rays), does not require large, heavy equipment (unlike magnetic resonance imaging), and has been shown through long use to be safe and effective when used by highly trained practitioners.

However, in current practice, ultrasound is basically an online two-dimensional (2-D) scanning procedure that produces a sequence of images under interactive hands-on control by the diagnostician. Each image represents a slice through the body at the corresponding ultrasound probe position. These images typically are difficult to interpret, requiring a trained ultrasonographer with years of experience to make more than the simplest diagnoses. This need for an expert interpreter makes it attractive to use ultrasound in a telemedicine setting, sending images from the patient's location to a skilled diagnostician somewhere else. However, with conventional 2-D ultrasound, considerable skill is required even to position the sensor probe, since this must be done interactively as diagnosis progresses. Thus it is problematic to use conventional 2-D

ultrasound in a telemedicine setting, due to the need for a highly skilled operator to scan the patient.

Three-dimensional (3-D) ultrasound imaging offers the potential to overcome these difficulties, thus providing a diagnostically valuable, low-cost, real-time imaging modality suitable for operation and use under emergency conditions by non-specialists. Because 3-D volumes show more context than 2-D slices, it becomes easier for users to understand spatial relationships and detect abnormal conditions. Positioning the sensor so as to acquire useful images is also easier with 3-D, because volumetric data can readily be rotated and realigned to good viewing positions, largely independent of the original sensor position. This potentially allows useful 3-D ultrasound data to be taken by an inexperienced operator, then transmitted to and interpreted by a remote expert.

2.2. CHRONOLOGY AND DISCUSSION OF ACCOMPLISHMENTS

In early 1994, the above considerations prompted Battelle to submit to DARPA, in response to solicitation BAA94-14, a proposal titled "Real-Time High Resolution 3-D Ultrasonic Imaging for Physiological Monitoring". This proposal laid out the vision of a three stage effort, roughly 8 years in length, leading to the development of an imaging "bed", roughly 10,000 square centimeters in size, containing an array of high resolution ultrasonic transducers and providing real-time 3-D visualization of many physiological and anatomical structures.

The first stage of this vision, and the focus of the proposal, was a planned 3-year project to develop a field prototype Advanced IMaging System (AIMS). This prototype would consist of a lightweight, portable ultrasonic imaging system envisioned as containing a 5 cm by 5 cm two-dimensional transducer array, computer hardware and software for real-time 3-D holographic image reconstruction and visualization, and a stereovision headset for 3-D image display. The system was envisioned as being used to rapidly detect foreign objects and bleeding in the body cavity, lungs, or extremities.

The Battelle proposal to develop an AIMS prototype was accepted by DARPA, and the project began in September 1994 with two major components:

- Research and develop advanced sensor technology, in particular, 2-D transducer arrays utilizing computational holographic focusing to acquire 3-D images in real time.

- Research and develop one or more fully functional prototype systems, suitable for clinical and/or field use, to investigate and demonstrate the utility of 3-D ultrasound as a medical imaging tool for use by non-specialist operators.

In early stages of the projects, it was planned that these two components would proceed sequentially, with the prototype system(s) being based on newly developed 2-D array transducers and thus appearing late in the project.

However, as the project progressed, it became apparent that a more productive strategy was to pursue both components in parallel, with prototype systems being based on currently available 1-D array transducer technology. This strategy was adopted in FY95, and research and development continued along both lines of research for the next three years.

In FY95, the primary activities and results were as follows:

- Sensor technology: Laboratory research using mechanically scanned simulations of 2-D transducer arrays confirmed that high quality images, fully focused everywhere in the 3-D field of view, could be obtained by using computational holographic focusing techniques in conjunction with large dense arrays (128x128) of high-frequency (5 MHz) transducers. (See Appendices A and B.) However, the supporting electronics and computational requirements to fabricate and use such large arrays for real-time imaging appeared beyond the reach of current technology. These requirements could be met with smaller, lower frequency arrays, such as 32x32 at 1MHz, and such arrays became the focus for sensor investigation in FY96.

- Prototype systems: a clinically usable 3-D ultrasound system based on "sequential B-scan" technology (mechanical sweep of a conventional ultrasound probe) was developed. This system was displayed at the October 1995 annual meeting of the AUSA (Association of the U.S. Army) in Washington DC, where it was favorably reviewed by many Army personnel. (See presentation slides, Appendix C) More

importantly, the system was placed into use in the clinic of Dr. Christian Macedonia at Madigan Army Medical Center in Tacoma, Washington, for an extended evaluation.

In FY96, research and development continued in both of these areas, but with a further shift of emphasis toward the development of field-usable systems. During this period (October 1995 through September 1996), activities fell primarily in four technical areas:

- Evaluation of 2-D array transducers operating in simultaneous source-receive mode at an array size and frequency consistent with then-current fabrication technology (32x32, 1 MHz), as applied to abdominal blood pooling using a custom phantom.

  Details of the laboratory portion of this study are contained in the report provided here as (Appendix D): "Evaluation of 3-D Ultrasound Holographic Imaging at 1 MHz for Detection and Visualization of Abdominal Blood Pooling Using a Mechanically Scanned Single Channel Transducer and Laboratory Phantoms".

  Several medical consultants reviewed this report (Dr. Richard Satava, Walter Reed Medical Center; Dr. Christian Macedonia, Madigan Army Medical Center; Dr. Stephen Carter, University of Washington; and Dr.Jonathan Ophir, University of Texas).

  The consensus opinion was that the images would be at best marginally useful for diagnosis, and that higher resolution (larger arrays and higher frequencies) would be required to construct a useful system. Since larger arrays and higher frequencies were not practical at that time using simultaneous source-receive mode, this line of research was tabled.

- Evaluation of computational holographic focusing used in conjunction with 2-D array transducers operating in receive-only mode (and thus capable of being fabricated in larger arrays operating at higher frequency). This evaluation produced positive results, concluding, "Three-dimensional imaging using reconstruction techniques developed at PNNL allows fully-focused three-dimensional imaging with an unlimited depth of field using a 2-D array, with or without a lens. If a lens is used, known aberrations that it causes may be removed from the images algorithmically."

Details of this study are provided in Appendix E: "Coherent Lens-based Image Reconstruction", D. M. Sheen, April 3, 1996.

- Evaluation of the FY95-produced "AIMS prototype", as used in clinical studies by Dr.Christian Macedonia at Madigan Army Medical Center.

  Results from this evaluation were not formally reported, but instead were incorporated directly into the requirements and system design of the MUSTPAC-1.

- Development and field-testing of a successor prototype 3-D ultrasound telemedicine system, called the MUSTPAC-1. This system preserved the high level architecture of the earlier "AIMS prototype", but replaced virtually every hardware and software component of the system with redesigned state-of-the-art elements.

  As delivered, the MUSTPAC-1 consisted of an 85-pound backpack unit containing everything necessary to operate in telemedicine mode when connected to any standard network supporting TCP/IP. It included the following subsystems and capabilities:

  - Hitachi's Model 905 portable, battery-powered, 2-D ultrasound scanner.
  - Battelle's 3-D Paddle electromechanical scanner.
  - TeleInViVo™ (Fraunhofer CRCG) volumetric visualization software, customized to meet this project's requirements.
  - A "virtual ultrasound probe", consisting of an Immersion Probe™ (Immersion Corporation) modified and interfaced by Battelle and Fraunhofer to provide the look, feel, and effect of a conventional ultrasound probe, when computationally reslicing volumetric data.
  - Silicon Graphics Indy™ computer and Presenter™ flat-panel display.
  - Drag-and-drop and graphical user interfaces for all functions.

Delivery and field demonstration of the MUSTPAC-1 was accomplished during July-September 1996. On July 8, Battelle delivered a MUSTPAC-1 system to the U.S. Army at Ft. Detrick. Following compatibility testing under supervision of the Center for Total Access (CTA, Ft.Gordon, Georgia), the MUSTPAC-1 was shipped to

Landstuhl, Germany, for further evaluation. On August 7, it was deployed to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia, while a second MUSTPAC-1 remained at LRMC (Landstuhl Regional Medical Center) to serve as a receiving station. Additional secondary receiving stations were established and used at Madigan Army Medical Center (Tacoma, WA, USA), Fraunhofer Center for Research in Computer Graphics (Providence, RI, USA), and Georgetown University Medical Center (Washington, DC, USA). The MUSTPAC-1 remained in Bosnia until it was redeployed to Georgetown on Sept.8.

This testing yielded the following results (as summarized to DARPA by email from Rik Littlefield to Rick Satava on Oct.21, 1996):

> In early July, this project delivered a prototype fully functional 3-D ultrasound telemedicine system called the MUSTPAC-1 (Military UltraSound, Three-dimensional and Portable, with Advanced Communication).
>
> MUSTPAC-1 provides the unique capability that high quality ultrasound scans can be taken at forward locations by an operator with no diagnostic skills, little training, and no online connection to an expert. The scans are then transmitted over any standard digital network to a qualified diagnostician, who interprets the scan using a ''virtual ultrasound probe'' that simulates a conventional real-time hands-on examination procedure. The virtual probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity (see below).
>
> In August 1996, the MUSTPAC-1 was deployed to the 212th MASH in Tuzla, Boznia. A second MUSTPAC (minus some packaging) was deployed to Landstuhl Regional Medical Center in Germany to serve as a ''buddy'' and consulting workstation for the Tuzla unit. During the 32-day deployment, approximately 72 scans of 38 patients were taken at Tuzla, with an additional 5 scans of 3 patients taken at Landstuhl. Scans were exchanged between Tuzla, Landstuhl, and Madigan Army Medical Center (Tacoma, WA, USA) using three different telecomm networks: the

Tuzla/Landstuhl/Tazar teleradiology net, the Tuzla TACNET, and an Inmarsat satellite link (Landstuhl to Washington DC).

The MUSTPAC system worked perfectly.

Trainup times at Landstuhl were observed to be under 5 minutes for diagnosticians to go from first contact with the equipment to making medical interpretations from the 3D datasets. In Bosnia, most of the scans were taken by people with no ultrasound experience, and less than 20 minutes exposure to the equipment. Image quality in the reconstructed scans was excellent.

Further information on the MUSTPAC-1 and the field test are provided in Appendix F: "MUSTPAC-1: 3-D Ultrasound Telemedicine System" (Web page) and Appendix G: "MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater"

As a result of the success of MUSTPAC-1, a change within scope was negotiated in late FY96 that adjusted the project's priorities to reduce the level of effort on 2-D array development, emphasizing instead further development of field-usable systems based on sequential B-scan technology.

In FY97, the principle activities and accomplishments under these refocused priorities were as follows:

1. further demonstration and publication of the prototype MUSTPAC-1 telemedicine system, including acceptance of one national award for Technology Innovation;
2. patent application for the MUSTPAC-1 architecture and system concept;
3. technical development of a third-generation prototype MUSTPAC-2 system;
4. laying groundwork for technology transfer of MUSTPAC-2; and
5. a small amount of continued research on sensor technology.

In more detail, FY-97 activities and accomplishments were the following:

1. Further demonstration and publication of MUSTPAC-1.

On May 31, 1997, largely as a result of the Germany/Bosnia field demonstration, MUSTPAC-1 won the Discover Award for Technology Innovation in Computer Hardware and Electronics (Discover Magazine, July 1997).

Demonstrations and discussions about MUSTPAC™ were invited and given — mostly with funding from other organizations — at the Association of the United States Army (AUSA) Annual Meeting (Washington, DC, 14-16 Oct 96), the AUSA Telemedicine Conference (Tysons Corner, VA, 4-6 Mar 97), the Military Medical Capabilities Conference (Knoxville, TN, 30 May 97), Grand Rounds at Walter Reed Army Medical Center and Georgetown University Medical Center (Feb 97 and May 97), the Spanish Society of OB/GYN meeting (Spain, Jun 1997), the Society of Minimally Invasive Therapeutics Meeting (Japan, Jul 97), the Medicine Meets Virtual Reality 5 (MMVR-5) conference (San Diego, CA, Jan 97), NASA Johnson Space Center (Houston, TX, Sep 96 and Jan 97), the Tribal Healthcare 2000 Conference (San Diego, CA, 15-17 Jul 97), and the U.S. Army Medical Command's Army Medical Department (AMEDD) Center and School Conference on Force Structure and Requirements in Telemedicine (Jul 1997).

During this period, the MUSTPAC-1 received a high level of attention and support from the public news media. Technical articles about MUSTPAC™, written by magazine staff, appeared in *Jane's International Defense Review* (Feb 97, pg.15, see Appendix I) and *Portable Design Magazine* (cover article, Jun 97, see Appendix H). A non-technical article, associated with the Discover Award, appeared in *Discover Magazine* (Jul 1997, pp.74-75.) In addition, many non-technical articles appeared in AP newspapers and on broadcast television, including CBS, CNBC, the Discovery Channel, and the Disney Channel.

2. Patent application.

On June 25, 1997, a patent application titled "Ultrasound Telemedicine System with Virtual Reality" was filed in support of the U.S. Department of Defense, covering the system concept and certain details of the MUSTPAC-1 system. A copy of this patent application was provided in the FY97 annual report.

3. Technical development of MUSTPAC-2.

As of October 1997, technical development of the MUSTPAC-2 was estimated as being approximately 70% complete, with the following major actions accomplished:

- Redesigned the 3-D Paddle electromechanical scanner to provide a fully sealed operating mechanism capable of immersion cleaning in standard disinfectant solutions. This was accomplished through the use of magnetic coupling of physical force from the internal drive mechanism, through an impermeable aluminum shell, to an external probe carrier.
- Replaced the Silicon Graphics computer, display, and keyboard with a Pentium laptop (Toshiba Tecra 740CDT) augmented with a separate video capture card (Osprey 100).
- Converted all software to run under the Solaris x86 operating system. (Solaris was an interim step, chosen to produce an operational prototype MUSTPAC-2 on the shortest possible schedule. The operating system for the final version of MUSTPAC™ was targeted as Windows NT.)

Although these changes were conceptually straightforward, some of them proved surprisingly difficult to accomplish. Video capture was an important example. Based on discussions with vendors in 1995 and 1996, MUSTPAC™ development staff believed that adequate video capture capability (640x480 pixels at 15 fps or better) would be conveniently available in Pentium laptops, either built-in or as a CardBus module. However, it turned out that neither capability was developed by industry according to the projected schedule, and after several false starts, the MUSTPAC™ project was eventually forced to use a PCI-bus video capture card. This in turn required adding an external PCI-bus capability to MUSTPAC-2, with attendant increase in size, weight, and complexity of packaging. In addition, a significant amount of programmer effort was required to adapt vendor-supplied video capture device driver software to the special needs of the MUSTPAC project.

In retrospect, it could be seen that rapid development of the high quality MUSTPAC-1 prototype was in large part due to the availability and selection of a particularly well-suited computer platform. The Silicon Graphics Indy computer used in the MUSTPAC-1 provided an integrated system, fully supported by a single vendor,

encompassing all of the required capabilities in video capture, display, computational speed, and communication software. It was a noticeable setback to the project that Silicon Graphics chose to discontinue the Indy, replacing it only with systems that were perceived as being too large and heavy to be viable for continued MUSTPAC™ development.

As of October 1997, however, many of the difficulties of platform conversion were overcome and a prototype MUSTPAC-2 system was operational. Further evaluation and development were planned for FY98, leading to projected completion of the MUSTPAC-2 final version in September 1998.

4. Technical transfer of MUSTPAC-2.

   Business discussions were held with 4 established ultrasound companies, leading to one agreement-in-principle for manufacture of MUSTPAC™ systems.

5. Development of sensor technology.

   An improved method was developed for computational holographic reconstruction of data obtained from a 2-D array sensor using off-axis illumination. This work was a small (3% of FY97 project expenditures) computational feasibility study designed to complement other DARPA-funded research exploring the possibility of using a receive-only dense array to achieve true real-time (e.g. 20 fps) high resolution 3-D acquisition.

In summary, at the end of FY97, project resources were focused almost completely on development of MUSTPAC™, with the goals of 1) having a Windows NT version completed by September 1998, and 2) further demonstrations and evaluations of the MUSTPAC™ technology.

During FY98 and FY99, the MUSTPAC™ technology was developed along the general lines planned in FY97, with refinements and redirections as determined by intermediate results such as those identified in the MUSTPAC™ presentation at the DARPA Ultrasound Workshop (Feb 11-13, 1998, Lansdowne, VA) (see Appendix J).

In March 1998, a contract modification and time extension was negotiated that formalized three deliverables for the remainder of the contract. Quoting from email

communications dated March 20, 1998, with Dr. Wally Smith, the DARPA program manager for this project, these deliverables were as follows. (Specific progress toward these deliverables is described in the following section.)

1. Mt. Everest expedition field test.

   Field-test MUSTPAC™ as part of the NASA/Yale Everest Extreme Expedition. One MUSTPAC™ unit will be ruggedized for cold and high altitude conditions. That unit and one MUSTPAC™ project team member will accompany the Everest Extreme Expedition to Base Camp, 17600 ft.

   At Base Camp and in transit, the MUSTPAC™ will be tested for its ability to collect medical ultrasound datasets and transmit those datasets over satellite links back to consulting sites in the U.S. for interpretation. This capability will also be demonstrated at the Technology, Entertainment, and Design TEDMED2 conference in Charleston, SC, on May 15, 1998.

2. Military demonstration and evaluation.

   Summary description (as submitted by Dr. Wally Smith for DARPA internal "highlights" list, February 18, 1998):

   > "Ultrasound Telepresence to be Demonstrated At Sea.
   >
   > The MUSTPAC development team led by Battelle is currently working with the U.S. Navy to place a MUSTPAC ultrasound telepresence system for at-sea testing on the aircraft carrier Enterprise when it deploys in Oct/Nov 1998, probably to the Mediterranean. Prior to deployment on the Enterprise, the MUSTPAC will reside at the National Naval Medical Center, Bethesda MD, for a period of 3-6 months, for evaluation, development, and vetting in the Navy's operational environment. NNMC, an integrated medical team composed of radiologists, surgeons, nurses, and other medical providers will develop protocols, collect and evaluate clinical data, and train the intended users. During deployment, ultrasound scans will be performed on the Enterprise by non-radiologists trained NNMC to use the equipment, and will be transmitted to NNMC evaluation by radiologists there. This effort was initiated and is being coordinated by CAPT Rick Bakalar, MD,

USN, Head of Telemedicine Department at NNMC, as requested by VADM Koenig. Clinical studies are being coordinated by CAPT Chuck Macri, MD, USN."

3. Demonstration at IEEE Ultrasonics Symposium (Sendai, Japan).

   The MUSTPAC, accompanied by one project team member, will be demonstrated as an "invited poster" at the 1998 international IEEE Ultrasonics Symposium.

In FY98, FY99, and FY00, progress toward the deliverables described above was as follows:

1. The Everest Extreme Expedition test and associated TEDMED2 Conference presentation were highly successful, despite a formidable collection of technical, administrative, and logistic hurdles to be overcome. In the end, a ruggedized MUSTPAC™ configuration based on a Fieldworks FW7666P rugged laptop and an Ausonics Impact VFI ultrasound scanner were taken to Mt. Everest Base Camp by Dr. Christian R. Macedonia (MAJ, US Army MC), co-inventor of the MUSTPAC™ system. At Base Camp Dr. Macedonia performed a total of 32 volumetric (3-D) scans and transmitted these to MUSTPAC™ diagnostic workstations positioned at Yale University and Walter Reed Army Medical Center (WRAMC). Communications were accomplished using a sat-com based electronic mail facility provided by Jim Bruton, the expedition logistics leader. In addition to the 3-D scans, Dr. Macedonia also collected a total of 292 still images (JPEG format) containing Doppler blood flow information relating to physiological adaptation to altitude. These results were discussed on May 15, 1998, during a real-time videoconference between Base Camp, WRAMC, and the TEDMED2 conference in Charleston, SC. See (Appendix K) for pictures of the Everest configuration. (Medical scientific results from the Everest mission will be published separately by Dr. Macedonia.)

2. The National Naval Medical Center (NNMC) demonstration and evaluation was repeatedly delayed due to a combination of administrative and staff availability factors. From a technical standpoint, progress was acceptable, with an initial installation at NNMC on May 15, 1998, followed by upgrades for increased functionality on June 5 and July 16. However, NNMC's clinical investigation

protocol was not approved by the Institutional Review Board (IRB) at NNMC until 3 Mar 1999, over a year after the study was first discussed and agreed upon in principle. As a result of these administrative delays, there was no progress on the actual clinical investigation during FY98, and very little during FY99. In late FY99, a further no-cost time extension through the end of FY00 was negotiated to give NNMC more opportunity to complete this study. However, the study continued to be impeded by staffing changes and low priority at NNMC. Furthermore, the potential relevance of this study to future MUSTPAC™ applications became progressively less clear, since the NNMC study was defined to use only the motor-driven linear scanner instead of the more recent freehand capability (see item #5, below). However, the very long time required for initial approval of the protocol argued against changing it at any point. In addition, the medical personnel involved were more comfortable with the concept of parallel scanning and preferred to have that constraint enforced by the motor-driven scanner. By July 2000, it became clear that there was no further value in formally continuing the NNMC investigation, so by agreement between NNMC, Battelle, and Dr. Wally Smith (DARPA project manager), the investigation was terminated with no further activity.

3. Demonstration at the 1998 IEEE International Ultrasonics Symposium, and subsequent publication of results was accomplished on schedule. See (Appendix L), R. J. Littlefield, C.R. Macedonia, J.R. Coleman, *MUSTPAC™ 3-D Ultrasound Telemedicine System*, 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, Oct.5-8, 1998.

For FY98-00, other notable activities and results (some negative) are as follows:

4. Conversion of the MUSTPAC™ system to Windows NT was completed.
5. MUSTPAC™ now includes a high quality freehand scan capability, utilizing a high precision mechanical arm as a 6-degree-of-freedom position sensor. This was accomplished by integrating into MUSTPAC™ a new acquisition and display software package called 3D FreeScan, a product of EchoTech 3D Imaging Systems GmbH (Hallbergmoos, Germany), then convincing EchoTech to modify their software to acquire positioning information using a high precision mechanical arm

(the MicroScribe arm from Immersion Corp., San Jose, CA) instead of a lower precision free-space magnetic sensor. In addition to greatly improving data quality, use of the mechanical arm also obviates earlier concerns about the impact on MUSTPAC™ of the active EMF cancellation used by Navy ships. Freehand scan capability using the mechanical arm was delivered to Dr. Chris Macedonia at Georgetown University in mid-November 1998, for use in Dr. Macedonia's study on amniotic fluid and cervical length measurements.

6. The TeleInViVo software from Fraunhofer CRCG has been replaced as the software of choice by the 3D FreeScan software from EchoTech (see previous item). At some future time, it is expected that TeleInViVo will be removed altogether from MUSTPAC™.

7. The MUSTPAC™ and Dr. Christian Macedonia appeared before the House Commerce Committee, Subcommittee on Health and Environment, June 5, 1998.

8. A possible application of MUSTPAC™ for prostate cancer detection & monitoring was identified. Dr. Chris Macedonia presented the MUSTPAC™ at the 70th Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine (JSUM) (Sendai, Japan, Nov.1997). While in Sendai, Dr. Macedonia collaborated with Dr. Yoshikatsu Tanahashi to utilize the MUSTPAC™ to reprocess video data recorded during an intraurethral prostate examination, producing a 3-D reconstruction and enabling subsequent reslicing at arbitrary angles. This resulted in a second presentation, by Dr. Tanahashi, at the 71st Semiannual Meeting of JSUM, highlighting MUSTPAC™ images generated by Richard J. (Rik) Littlefield of Battelle / Pacific Northwest National Laboratory (PNNL) from videotapes sent to him by Dr. Tanahashi. On this same topic, Rik Littlefield attended the workshop "Transperineal Brachytherapy for Early Stage Prostate Cancer" held by Northwest Hospital (Seattle, WA, Jan.12-13, 1998).

9. A possible application for MUSTPAC™ in screening for thyroid nodules among Chernobyl victims was identified by Dr. Richard Satava, previously with DARPA and currently at Yale. This application was not pursued due to lack of funding.

10. The MUSTPAC™ patent application, filed June 25, 1997, was rejected on the grounds of obviousness compared against patent #5,609,485, "Medical Reproduction System", by Mark Bergman et.al., granted Mar.11, 1997 and assigned to MedSim, Ltd. of Israel. This patent was unknown to the project team at the time of the MUSTPAC™ filing (and, obviously, MUSTPAC's earlier development). Fortunately, the MedSim patent specifically restricts its claims to the application domain of training, so the existence of this patent apparently does not create any issues for use of MUSTPAC™ in medical practice.

11. No commercialization partner has been identified, although several letters of interest were received in response to a CBDNet notice published in March 1999.

12. Several individual technology improvements developed or identified by this project have been transferred into the commercial domain. These include:

    - The "virtual ultrasound probe" user interface specification, adopted by EchoTech for their 3D FreeScan product.
    - Use of the high precision mechanical arm (Immersion MicroScribe™) for 3D data acquisition, also adopted by EchoTech for 3D FreeScan.
    - Medical quality video capture by a PCMCIA-format interface card, adopted by EchoTech for 3D FreeScan.

13. At NASA's invitation, Richard J. (Rik) Littlefield presented MUSTPAC at NASA's Seminar in Ultrasound: Applications and Implications in Human Spaceflight, Houston, TX, July 25-26, 2000.

14. Under separate travel funding, but utilizing MUSTPAC™ equipment, presentations were given at the following conferences / workshops:

    - Pacific Medical Technology Symposium (PacMedTek), Honolulu, HI, August 18-21, 1998, presented by Larry Skelly, PNNL and Dr.Chris Macedonia, US Army Medical Corps.
    - U.S. Dept of Energy (DOE) Biomedical Technologies Exposition, Washington DC, April 20, 1999, presented by Richard J. (Rik) Littlefield, PNNL.

- Advanced Technology Applications to Combat Casualty Care (ATACCC-98), Fort Walton Beach, FL, November 17-19, 1998, presented by Laura Curtis, PNNL.

15. Project review meetings were held or attended as follows:

    - Advanced Medical Technologies Workshop, San Diego, CA, Jan 28-29, 1998.
    - MUSTPAC Expert Panel Review, ISIS Center, Georgetown University, Washington, DC, Feb 10, 1998.
    - DARPA 40th anniversary celebration, Arlington, VA, April 6, 1998.
    - Image Conference, Scottsdale, AZ, Aug 6, 1998.

16. Discussions regarding potential follow-on projects (separately funded) were held as follows:

    - McKennan Hospital (Sioux Falls, SD): August 25, 1998; November 16, 1998; December 4; 1998; April 14, 1999.
    - South Dakota Congressional briefing, regarding McKennan Hospital proposal, Georgetown University ISIS Center, Washington DC, December 9, 1997.
    - Mercy Hospital (Darby, PA): August 31, 1998; June 8, 1998; February 17, 1999.

17. Two follow-on projects for MUSTPAC™ have been developed:

    - For McKennan Hospital in Sioux Falls, South Dakota, using a mix of U.S. Department of Agriculture and non-government matching funds arranged by McKennan, Battelle will develop and place several MUSTPAC™ systems into McKennan's existing telemedicine system. Getting this project in place has been repeatedly delayed by lack of non-government funds to match the USDA contribution. As of this writing (August 2000), this project is expected to be finalized in September 2000.
    - For Mercy Hospital in Philadelphia, using government funding coordinated through TATRC, Battelle will place one unit for clinical evaluation, with follow-on phases to place and evaluate additional units for emergency care. This project

officially began on June 14, 1999. See Appendix M for a complete description of this project.

IRB References

All investigations involving human subjects in this project have been performed in adherence to applicable policies of Federal Law 45 CFR 46, approved and monitored by Institutional Review Boards at the Pacific Northwest National Laboratory (PNNL) and other participating organizations as follows:

- Everest Extreme Expedition: Georgetown University Medical Center (GUMC) IRB approval #98-113; PNNL IRB approval #94-6.
- National Naval Medical Center, IRB approval #B98-070; PNNL IRB approval #94-6-5.
- Amniotic fluid and cervical length measurements: GUMC IRB approval #179-97; PNNL IRB approval #94-6.

3. KEY RESEARCH ACCOMPLISHMENTS

Numerous research accomplishments have been described in detail in the previous section. Over the entire duration of the project, key accomplishments can be summarized as follows:

- Laboratory demonstration of high resolution optimally focused 3-D ultrasound imaging using a mechanically simulated dense 2-D array transducer with computational holography image reconstruction.
- Theoretical development of methods to merge computational holography image reconstruction with lens-based imaging, offering the potential for increased depth of focus in lens-based systems using high resolution 2-D array receivers with a separate transmit transducer.
- Development and demonstration of the MUSTPAC-1 ultrasound telemedicine system, including successful field evaluation in Bosnia and Germany, leading to the 1997 Discover Award in Computer Hardware and Electronics and other awards and publications.

- Development of the MUSTPAC-2 system and successful field demonstration as part of the Everest Extreme Expedition.

- Development of the MUSTPAC-3 ultrasound telemedicine system and associated technology transfer, leading to off-the-shelf availability of hardware and software for the 3-D scanning and "virtual probe" reconstruction capabilities of MUSTPAC.

4. REPORTABLE OUTCOMES

- 12 publications; see publications section below.
- 1 patent application, number 08/882,178 dated June 25, 1997; see item #10 above.
- 25 meetings and conference presentations; see details above in discussion of project chronology.
- Additional funding sought, roughly $800K in two projects; see item #17 above.

5. PUBLICATIONS

- Macedonia CR. December 4, 1998. *The Philosophy and Practice of Medical Telepresence in Rural Health*, Sioux Falls SD (with Satellite Broadcast to the quad state region in cooperation with the Indian Health Service).

- Macedonia, CR. 1998. "Telemedicine and ultrasonography: making waves," *Ultrasound Obstet Gynecol*; 12:1-2. (See Appendix G, in the 1999 Annual Report.)

- Macedonia CR, J Collea, J Sanders. 1998. "Telemedicine Comes to Obstetrics and Gynecology", *Contemp Ob* 43:92-111.

- Macedonia C, RJ Littlefield, J Collea, H Landy, R McClaren, K Lewis, I Zalud, L Bartholomew, JC Pezzullo, G Eglinton. January, 1999. *A comparison of standard endovaginal cervical length sonography to free-hand acquired three-dimensional endovaginal sonography.* Abstract to the Society of Maternal Fetal Medicine (formerly SPO), San Francisco CA.

- Macedonia CR., RJ Littlefield, J Coleman, RM Satava, T Cramer, G Mogel, and G Eglinton. 1998. "Three-dimensional ultrasonographic telepresence", *Journal of*

Telemedicine and Telecare, 4:4, 224-230. (See Appendix F in the 1999 Annual Report.)

- Macedonia CR, SK Mun, RJ Littlefield. November 1997. *Telemedicine and Ultrasound: A Comparison of Two-dimensional and Three-dimensional Imaging Techniques*. 70th Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine, Sendai Japan.
- Littlefield RJ. April 20, 1999. *MUSTPAC™ 3-D Ultrasound Telemedicine Imaging System*, DOE Biomedical Technologies Exposition, Washington DC. (See Appendix N.)
- Littlefield RJ, CR Macedonia, JR Coleman. 1998. *MUSTPAC™ 3-D Ultrasound Telemedicine/Telepresence System*, 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, October 5-8. (See Appendix L.)
- Littlefield RJ, Heiland RW, Battelle, PNNL. 1996. *Virtual Reality Volumetric Display Techniques for 3-D Medical Ultrasound*, prepared for Medicine Meets Virtual Reality: 4 (MMVR: 4), San Diego, California, January 17-20, 1996. Published in *Medicine Meets Virtual Reality: 4 / Health Care in the Information Age*, IOS Press, pp. 461-470. (See Appendix B.)
- Sheen DM, Collins HD, Gribble RP, Battelle PNNL. 1996. *Wideband Holographic 3-D Ultrasonic Imaging of Breast and Liver Phantoms*, prepared for Medicine Meets Virtual Reality: 4 (MMVR: 4), San Diego, California, January 17-20, 1996. Published in *Medicine Meets Virtual Reality: 4 / Health Care in the Information Age*, IOS Press, pp. 461-470. (See Appendix A.)
- Tanahashi, Yoshikatsu, M.D., Ph.D., Christian Macedonia, M.D. May,1998. *Formatted and Retrievable Imaging Evaluation for Neoplasm and Disease Screening High-resolution Intraurethral Prostagrams (FRIENDSHIP)*, presented at the 71st Semiannual Meeting of the Japanese Society of Ultrasonics in Medicine, Yokahama Japan.
- Dr. Christian R. Macedonia. June 5, 1998. Testimony before the House Commerce Committee, Subcommittee on Health and Environment.

6. SUMMARY AND CONCLUSIONS

The goal of this project was to develop a field prototype medical imaging system utilizing 3-D volumetric ultrasound. This goal was pursued with a combination of 1) research on holographic techniques using 2-D sensor technology and computational reconstruction, and 2) development of clinically usable and field-testable telemedicine systems based on mechanical scan of conventional 1-D sensor arrays. The primary research product was the MUSTPAC™ (Medical UltraSound, Three-dimensional, Portable, with Advanced Communications). MUSTPAC™ is an ultrasound telemedicine system that allows a patient to be scanned at any convenient location by an operator with limited training and no ultrasound diagnostic skills, then have those scans analyzed by a diagnostic expert at a center of excellence at any location. This technology may have widespread application in both military and civilian rural and emergency healthcare, resulting in both improved quality of care and reduced costs. Several uncertainties remain, one of which is that the medical community still needs to determine what types of medical conditions can be effectively addressed by MUSTPAC™. In any case, acceptance will ultimately be determined by a complex interplay of issues involving economics, infrastructure, and regulation, which are beyond the scope of study and effect for this project. This project was technically successful, but the technology is not yet widely accepted, and it is still an open question whether MUSTPAC™ or any other ultrasound technology will be widely adopted for telemedicine.

7. PERSONNEL RECEIVING PAY

The following employees of Battelle / Pacific Northwest National Laboratory charged against this project during its span of 5 calendar years:

Management	
John Deffenbaugh	Manager
Sheila Stade	"
Jerry Posakony	Program Manager
Michael Lind	"
Stanley Neuder	"
Sam Stevens	"
Larry Skelly	"
Earl Heister	Technial Resource Manager

Wayne Lechelt	Technical Group Manager
Science / Engineering Staff	
Steve Doctor	Chief Engineer
David Clark	Sr Engineer
John Ellis	"
Michael Dodson	"
Stanley Owsley	Engineer
Leslie Kirihara	"
Garry Dewinkle	Engineer - Safety
Mark Hansen	Sr Research Engineer
Jesse Willet	"
Jonathan Smalley	"
Joseph Tucker	"
Kevin Adams	Sr Research Engineer
Keith Middleton	"
Darren Curtis	"
Jim Prince	Staff Engineer
Thomas Hall	"
Larry Gerhardstein	Staff Scientist
Rik Littlefield	"
Dave Sheen	"
Paul Keller	"
Paul Blowers	Research Scientist
Kevin Simmons	"
Derek Hopkins	"
Randy Heiland	"
Karol Miaskiewicz	"
Sean Sparks	"
Eric Lopresti	"
Kathy Moore	"
George Schuster	"
Dale Collins	"
Maureen Gilmore	Sr Research Scientist
Dave Devaney	"
Laura Curtis	"
Mike Alderson	"
Michael Blackford	"
Lamarr Stoops	"
John McCall	"
Mary Brewster	"
Dick Pappas	"
Gary Black	"
Mark Hinchee	"
Richard May	"
Dave Rex	"
Mary Sue Hoxie	"
Greg Thomas	"
Pat Grengs	"
Timothy Schiebe	"
Newton Brown	"
Science & Engineering Associates	
Parks Gribble	Science & Engineering Associate
Robert Sullivan	"

Joe Harris	"
Michael Watts	"
Ron Severtsen	"
Robert Bowey	"
Paul Tomeraasen	"
Lindsey Todd	"
Leonard Shotwell	"
Ted Tanasse	"
Becky Kennedy	"
Tom Kiefer	"
Leslie Schwartz	"
Kim Lessor	"
Larry Reid	"
Paul Rhode	"
Tonya Martin	"
Kathy Poeppel	"
Melody Maynard	"
Albert Mendoza	"
Karen Creel	"
Kevin Gervais	"
Juan Valencia	"
Jeff Cole	"
Kevin Dallman	"
Doug Riechers	Technician
J Scott Caldwell	"
Administrative Support Staff	
Carol Sharp	Administrator
Dave Niesen	"
Kathy Kindall	"
Maude Wickline	"
Sherry Davis-Cross	"
Valerie Hamilton	"
Kathy Rightmire	Clerk
Linda Fastabend	"
Regina Orgill	"
Marsha Brehm	Secretary
Lori Jordan	"
Lisa Roberts	"
Diana Soper	"
Chrissy Garcia	"
Karen Salisbury	"
Debbie Widman	"
Phadera Hutcheson	"
Sharon Suarez	"
Ben Barnett	"
Mary Cliff	"
Erin Pratt	"
Nicole Lemburg	"
Kari Fausi	"
Suzette Hampton	"
Lisa Smith	"
Mary Glass	"
Gloria Fitzgerald	"

Jesse Sharp	"
Mary Glass	"
Christina Cliff	"
Linda Krumbah	Sr Administrative Secretary
Delores Netter	"
Teresa Fettkether	"
Twilla Knowles	"
Kay Gregory	"
Priscilla Yamada	"
Cathy Stephens	"
Ana Lundeby	"
Steve Matsumoto	Communication Specialist
Susan Widener	"
Lee Prince	"
Shannon Osborn	"
Colleen Winters	"
Jodi Melland	"
Wayne Crosby	"
Kay Hass	Text Processor
Tanya Matthews	"
Bob Willard	Contracts Team Lead
Crafts	
Alice Versteeg	Materials Coordinator
Dave Newton	Crafts
Elmer Sullivan	"
Wayne Douglas	"
Leslie Woodcock	"
Claudia Mace	"
Douglas Conner	"
Richards Mays	"
Michael Deines	"
William Higgins	"
Terry Kirkwood	"
Mark Townsend	"
Joe Killinger	"
Larry Waddell	"
Frank Bittrick	"
Randy Lemasters	"
James Clark	"
John Young	"
John Freese	"
Wayne Crayne	"
Clayton Pettit	"
Jose Canales	Storekeeper
Brent Gillard	"

APPENDIX A

Appendix A: ***Wideband Holographic 3-D Ultrasonic Imaging of Breast and Liver Phantoms, prepared for Medicine Meets Virtual Reality: 4 (MMVR: 4), San Diego, California, January 17-20, 1996. Published in "Medicine Meets Virtual Reality: 4 / Health Care in the Information Age", IOS Press, 1996, pp. 461-470.***

Wideband Holographic 3-D Ultrasonic Imaging of Breast and Liver Phantoms

David M. Sheen (dm_sheen@pnl.gov)
H. Dale Collins (hd_collins@pnl.gov)
R. Parks Gribble (rp_gribble@pnl.gov)
Battelle, Pacific Northwest Laboratories

Abstract

Wideband ultrasonic 3-D holography is a unique technique for volumetric imaging with extremely high lateral and depth resolution. The large frequency bandwidth, which is typically 25% to 100%, provides excellent depth resolution. The synthetic aperture provides optimum lateral resolution of one-half wavelength at the pulse center frequency. Wideband impulse holography is a multi-frequency detection and imaging technique where the reflected target's broadband time waveform signals are recorded over a defined aperture. The signals are then decomposed into their discrete frequency components as single frequency holograms, combined in the spatial frequency domain, and reconstructed into a 3-D composite image. The composite image may then be viewed with stereo glasses in 3-D. Recent 3-D holographic images of human female breast and liver phantoms with internal cysts (5 to 10 mm) at 5 MHz illustrate the efficacy of this technique for medical ultrasound 3-D volumetric imaging. A video of the breast and liver phantoms may be presented at the meeting.

1. Introduction

Ultrasonic medical imaging systems presently in use form two-dimensional images of slices (B-scans) through the human body. These systems are very useful, particularly since they are real-time and form many images per second. This allows the operator to quickly scan through volumes in the body looking for the anatomical features of interest.

Three-dimensional ultrasonic imaging offers significant benefits over conventional B-scan imaging systems for medical systems. One benefit is that a complete scan could be obtained quickly from the volume of interest, with analysis performed in detail at a later time. This analysis could include 3-D rendering with rotation, tilt, as well as the display of image slices through the 3-D image. Some of these image slices could be selected at angles that are not possible with conventional B-scanners due to the lack of a suitable acoustic window through the body at that angle. These tools could aid in the analysis of the images and subsequent medical diagnosis. Another benefit is that true 3-D imaging could be high-resolution in all three-axes. B-scan systems are typically high-resolution only in the two axes displayed in the image, with the elevation direction lower resolution due to the height of the transducer array.

Three-dimensional image acquisition requires that ultrasonic data be gathered over two lateral dimensions with the time axis related to the third image axis. This data can be acquired using focused transducers, or using unfocused transducers combined with computer processing to focus the data.

Current real-time B-scan systems use curved or linear arrays of transducers which are time-delayed to form a scanning focused beam. This data is focused on transmit and receive and requires little or no

computer processing to form the image. This type of focusing could be extended to three-dimensions by scanning or rotating the B-scan array. This technique would not provide optimal resolution in the direction of the scan since only a fixed focus would be available along that axis. A more sophisticated way to modify the time-delay focused systems to 3-D would be to fabricate a 2-D array of transducers, with time delay focusing along both axes. Such arrays are currently not available with the large numbers of elements required for medical use.

Wideband holography is another technique that may be used to focus ultrasonic image data. This technique gathers the data by using an unfocused (spherically diverging) beam with the image formed entirely in post-processing using computer processing to form the images. This technique can be used to form images of the highest possible resolution, since each point in the three-dimensional image is focused optimally. It is not required to separate the image space into distinct focal zones. Wideband holography is similar to traditional acoustic holography [Goodman; Hildebrand and Haines; Hildebrand and Brenden], with the extension to full wideband processing for true depth resolution. A three-dimensional image will require that the diverging beam transducer be scanned over a two-dimensional aperture, or that a linear array be scanned over a linear aperture. A 2-D transducer array could be used to form images with no mechanical scanner required. However, suitable arrays are not yet available. For the experimental results presented in Section 4, a single transducer was scanned over 2-D aperture to obtain the 3-D image data.

At this stage, our research has been directed at obtaining 3-D ultrasonic images of the highest resolution using medical imaging phantoms. As presently implemented, our experimental techniques require more time than would be available for practical medical imaging systems. Ongoing efforts are directed at modifying these techniques to allow for fast data acquisition and processing. This work is part of an ARPA-sponsored research project directed at the development of 3-D ultrasonic imaging systems useful for the diagnosis of battlefield injuries.

2. Wideband Holographic Imaging Technique

Wideband holographic imaging is a means of forming high resolution three-dimensional images of targets from wide-bandwidth data gathered over a two-dimensional planar aperture. The target to be imaged is illuminated over a planar aperture using an unfocused, or diverging, coherent source such as an ultrasonic transducer. The transmitted diverging beam impinges on the target resulting in echoes which are recorded by the transducer. The reflected or echoed signal is then recorded coherently (digitized) and stored in a computer memory. The complete set of unfocused data can then be used to mathematically reconstruct a fully focused three dimensional image of the target's reflectivity function.

A highly efficient algorithm has been developed at Battelle that may be used to perform this image reconstruction. This technique relies extensively on the use of Fourier Transforms which may be computed very efficiently using the Fast Fourier Transform algorithm. The reconstruction method allows for wide relative bandwidths and allows for the targets to be near to the scanned aperture. No far-field approximations are made. Therefore, the only limitation on the resolution obtained is the diffraction limited resolution imposed by the wavelength, source and receiver beamwidths, size of aperture, and distance to the target. This method is similar to single frequency holography [Goodman; Hildebrand and Haines; Hildebrand and Brenden], with the extension to wideband illumination, which allows for true three-dimensional high-resolution imagery from a two-dimensional planar aperture.

Data collection is performed by scanning a transmitting source and receiver over a rectilinear planar aperture which has one or more targets within its field of view. The image reconstruction algorithm described in this section is an extension of work by Soumekh [1991, 1994]. Soumekh derived a wideband synthetic aperture imaging algorithm which reconstructs data from a linear aperture into a two-dimensional image. This work extends this derivation by making the aperture planar instead of linear which allows for a fully three-dimensional image reconstruction.

A full mathematical derivation of the reconstruction algorithm is beyond the scope of this paper; however, an overview of the technique will be given. The transducer is assumed to produce a diverging beam. At a modest distance from the transducer, this beam is approximately a spherical wave. This spherical-wave can be mathematically decomposed into a superposition of plane-wave components emanating from the source over all possible angles. The plane-wave decomposition is performed in the frequency domain, so the recorded time-domain data are Fourier Transformed to obtain the frequency domain data. After plane-wave decomposition the spherical wave phase function is expressed in terms of a superposition of linear phase functions. These linear phase functions are plane waves and may be grouped as Fourier integrals and inverted using multi-dimensional Fourier Transforms. Thus, an efficient image reconstruction is possible based almost entirely on the Fourier Transform. For computer implementation, the Fast Fourier Transform algorithm is used resulting in a very efficient image reconstruction algorithm.

The expected lateral resolution for the wideband holographic imaging system is approximately one-half wavelength times the F-number. The F-number is equal to the range to the target divided by the aperture width, or is determined by the beamwidth of the transducer. The longitudinal range resolution is determined by the pulse width or bandwidth of the system, which are inter-related. The range resolution may be expressed as $v/2B$, where v is the velocity of sound in the medium, and B is the bandwidth of the system. The range resolution may also be expressed as $vT/2$ where T is the pulse width in time. For a wideband system, both the lateral and range resolutions obtained are on the order of one-half to four wavelengths at the center frequency.

3. Experimental Imaging System

An experimental imaging system was assembled to gather wideband holographic ultrasonic data from various medical ultrasonic phantoms. This system consists of a high-resolution two-axis mechanical scanner, a water bath, an ultrasonic transducer assembly operating at 5 MHz with associated transmit and receive circuitry, and a computer with A/D converter.

The mechanical scanner is high-resolution and can scan up to 15 cm on each of two axes. The scanner holds the transducer a short distance above the target. The water bath allows the ultrasonic waves to be coupled to the target, while still maintaining a planar scanned aperture. An attractive feature of the water-bath system is that the shape of the target is undisturbed and can be imaged along with the underlying features of the target. This is not possible using conventional B-scanning techniques in which the scanner is directly coupled to the target and therefore does not accurately image the shape of the target.

The transducer assembly consists of two small (60 mil) circular flat transducers operating at 5 MHz. At this frequency the transducers are approximately 4 wavelengths wide, and produce a beamwidth of approximately 14 degrees. This beamwidth results in an F-number approximately equal to 4. An F-number of 4 will produce lateral resolution of approximately 2 wavelengths. For the imaging results presented in the next section, the transmitted waveform consisted of 8 wavelengths at 5 MHz. This results in a depth resolution of approximately 4 wavelengths, or twice the lateral resolution dimension.

The transmitted waveform (8 cycles) has a bandwidth of approximately 25%. At 5 MHz the wavelength of ultrasound in water is approximately 0.3 mm. This configuration therefore has a lateral resolution size of approximately 0.6 mm, and a depth resolution size of approximately 1.2 mm. The depth resolution could easily be improved by reducing the number of cycles transmitted. This was not done so that the size of the overall data set would be more manageable.

The receiver circuitry amplifies the target echoes prior to A/D conversion. If digitized directly, the received 5 MHz waveform would require sampling rates in excess of at least 10 MHz and more typically 20 MHz (allowing for 4 samples per wavelength). Since the bandwidth of our system is only approximately 25%, the sampling rate can be reduced considerably by coherently demodulating the received signal. This is done by mixing it in quadrature with the source oscillator (5 MHz) used to generate the 8 transmitted cycles, to yield in-phase (I) and quadrature (Q) demodulated signals. The full-bandwidth of the system is 25% of 5 MHz or 1.25 MHz. Thus, the maximum frequency in each of the I and Q signals is 0.625 MHz. The demodulated I and Q signals must be sampled at a rate of at least 1.25 MHz or more typically 2.5 MHz. Our system was configured with a sample rate of 5 MHz to allow flexibility to vary the system bandwidth without changing the data sampling rate.

Once a complete scan of the target has been digitized and stored in the computer, the computer image reconstruction algorithm discussed in the previous section is applied to the data. The numerical reconstruction is performed using a high-speed arithmetic co-processor. The resulting 3-D image data can then be displayed on the host computer as 2-D slice images, or processed further for 3-D rendered images.

4. Imaging Results

To evaluate the effectiveness of the wideband holographic imaging technique on targets as realistic as possible, ultrasound phantoms of the human female breast and human liver fabricated by ATS Laboratories were selected. The breast phantom is of a type used to train physicians for ultrasound guided biopsies. It contains simulated cysts which are in the form of 10 mm diameter spheres. The liver phantom is constructed in a similar fashion to the breast phantom. A simulated gall bladder with gall stones is included in the phantom as well as simulated cysts.

Unlike conventional B-scanners, the output of the wideband holographic imaging system is a fully-focused 3-D image. In this paper, we will, however, not attempt to render the data in a three-dimensional fashion but will simply examine various slices through the reconstructed 3-D images. Two-different orthogonal image slices will be shown. B-scan slices are slices through the data set which are perpendicular to the plane containing the scanned aperture. C-scan slices are slices through the data set which are parallel to the scanned aperture. It should be pointed out that the B-scan view is similar to that from conventional B-scanners, except that the thickness of the slice is much thinner in the 3-D B-scan view.

The data presented in this paper has also been rendered in a 3-D manner and will be presented in a separate paper at this conference by R. Littlefield, R. Heiland, and C. Macedonia.

Figures 1 and 2 show image slices from the reconstructed 3-D image of the human breast phantom imaged at 5 MHz. This 3-D image was obtained from an 80 mm by 80 mm by 27.5 mm scan of breast phantom placed in a water bath. The phantom was scanned from above, i. e. the time axis corresponds to the vertical image axis in Figure 1. To avoid aliasing, a large number of data samples were taken with 512 sample points in both lateral dimensions and 256 samples (at 5 MHz sampling) in time. The first image in Figure 1 shows the a cross-section slice of the breast phantom which contains only

background scatterers. The second image clearly shows a 10 mm spherical simulated cyst. There is also some shadowing below the cyst. The third image shows another cyst near the bottom right. The fourth image clearly shows the outline of the breast along with two cysts. The nipple and the area just to the right of the nipple are relatively bright in this image. This is due to the normal to the surface of the breast being aligned with the transducer which results in a specular reflection at these points. This type of feature would not be present if the transducer were directly coupled to the target, as is commonly done with conventional imaging. The fifth image shows a bright cyst (echogenic) as well as a darker cyst (non-echogenic).

Figure 2 shows C-scan slices from the reconstructed 3-D image of the human breast phantom. These images clearly resolve the various simulated cysts. Some of the darker circular areas are shadows caused by bright cysts blocking some of the ultrasonic energy, while others are due to non-echogenic cysts. The high lateral resolution is demonstrated by the bright point scatterers located on the surface of the breast.

Figure 3 shows C-scan image slices from the reconstructed 3-D image of the human liver phantom imaged at 5 MHz. This 3-D image was obtained from a 75 mm by 100 mm by 60.5 mm scan of liver phantom placed in a water bath. To avoid aliasing, a large number of data samples were taken with 512 sample points in both lateral dimensions and 256 samples (at 5 MHz sampling) in time. The second image in Figure 3 clearly shows a non-echogenic (dark) spherical cyst. The third, fourth, and fifth images clearly show the simulated gall bladder, along with several simulated gall stones. As in Figure 2, the high lateral resolution is demonstrated by the bright point scatterers seen in several of the images in Figure 3.

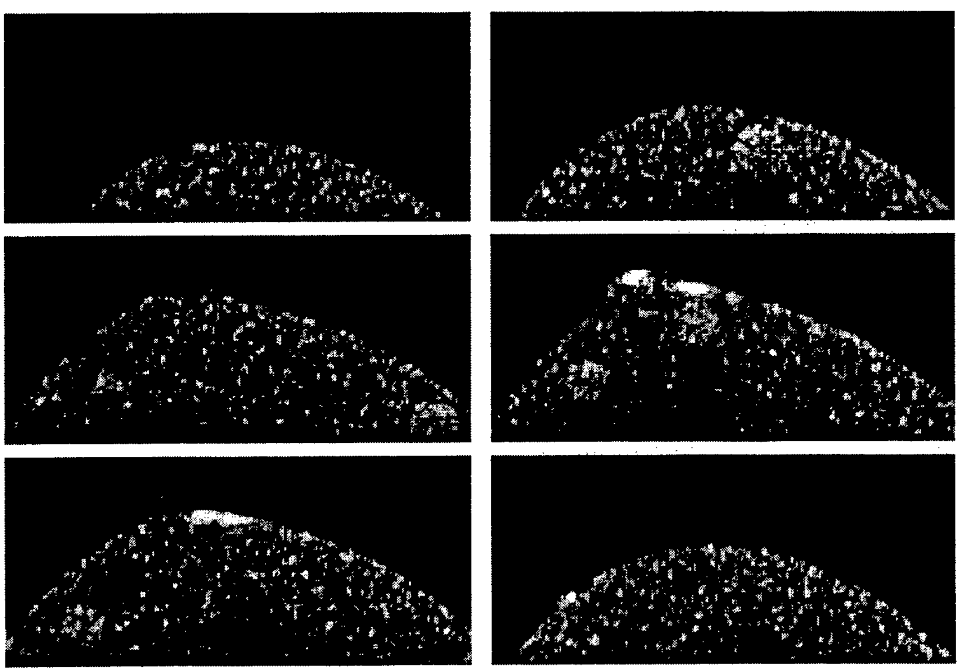


Figure 1. 3-D ultrasonic images of human breast phantom at 5 MHz (B-scan view shown).

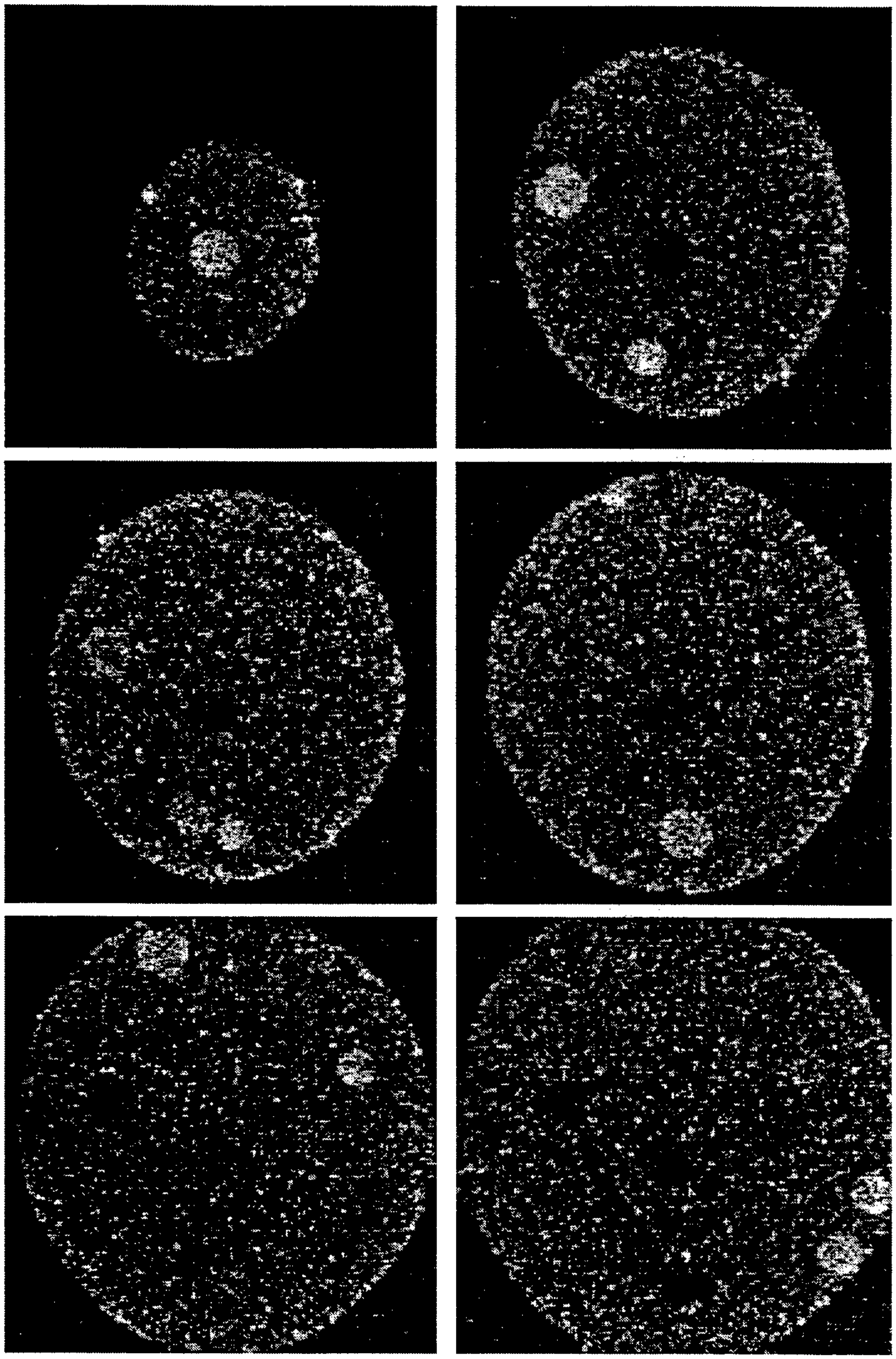


Figure 2. 3-D ultrasonic images of human breast phantom at 5 MHz (C-scan view).

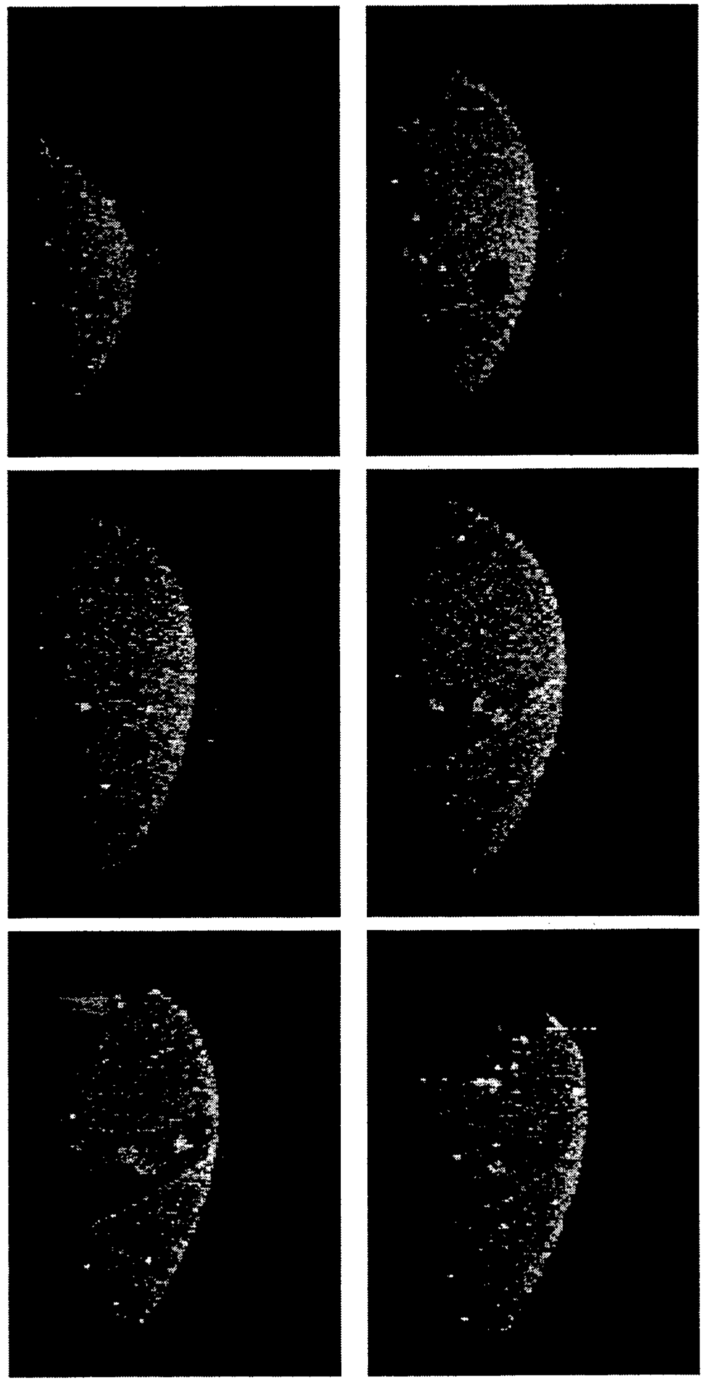


Figure 3. 3-D ultrasonic images of human liver phantom at 5 MHz (C-scan view shown).

5. Conclusions

High-resolution three-dimensional ultrasonic imagery of breast and liver phantoms has been demonstrated. The wideband holographic imaging technique has been shown to provide high resolution simultaneously in both lateral dimensions as well as the range dimension. This high resolution is obtained for all positions throughout the image. This is an improvement over conventional systems which use one or more fixed focal zones to obtain the focused image. In

addition, conventional B-scanners will have rather poor resolution in the elevation direction, i.e., the direction normal to the image plane. Difficulties, however, currently prevent the application of this type of technique for clinical use. At high frequencies (such as 5 MHz) the data set is very large and cannot be reconstructed quickly with low-cost computer systems. Furthermore, the velocity of sound limits the number of pulses that may be transmitted per second which limits the frame rate of a 3-D imaging system. Despite these limitations, we believe that synthetic focusing techniques such as the wideband holographic technique, or variations, will play a role in the development of 3-D clinical ultrasonic imaging systems.

6. Acknowledgments

This work was supported by funds from the Advanced Research Projects Agency (ARPA), contract number DAMD17-94-C-4127. We would like to thank Dr. Rick Satava of ARPA for his consistent encouragement and oversight of this work.

7. References

Goodman, JW. 1968. *Introduction to Fourier Optics.*: McGraw-Hill, San Francisco, California.

Hildebrand, BP, and BB Brenden. 1972. *An Introduction to Acoustical Holography.* Plenum Press, New York.

Hildebrand, BP, and KA Haines. 1969 "Holography by scanning." *J. Opt. Soc. Am.* 59(1):1.

Soumekh, M. 1991."Bistatic synthetic aperture radar inversion with application in dynamic object imaging." *IEEE Transactions on Signal Processing* 39(9):2044 - 2055, September.

Soumekh M. 1994. *Fourier Array Imaging.*: Prentice Hall, Englewood Cliffs, New Jersey.

APPENDIX B

Appendix B: ***Virtual Reality Volumetric Display Techniques for 3-D Medical Ultrasound, prepared for Medicine Meets Virtual Reality: 4 (MMVR: 4), San Diego, California, January 17-20, 1996. Published in "Medicine Meets Virtual Reality: 4 / Health Care in the Information Age", IOS Press, 1996, pp. 461-470.***

Reprinted with permission.

Virtual Reality Volumetric Display Techniques for 3-D Medical Ultrasound

Richard J. Littlefield (rj_littlefield@pnl.gov)
Randy W. Heiland (rw_heiland@pnl.gov)
Battelle, Pacific Northwest Laboratories

Dr. Christian R. Macedonia (christian_r.macedonia@mamc.chcs.amedd.army.mil)
Madigan Army Medical Center

Abstract

Ultrasound imaging offers a safe, inexpensive method for obtaining medical data. It is also desirable in that data can be acquired at real-time rates and the necessary hardware can be compact and portable. The work presented here documents our attempts at providing interactive 3-D visualization of ultrasound data. We have found two volume rendering visualization packages to be quite useful and have extended one to perform stereographic volume visualization. Using a relatively inexpensive pair of commercial stereo glasses, we believe we have found a combination of tools that offers a viable system for enhancing 3-D ultrasound visualization.

Introduction

Ultrasound is the imaging modality of choice in many medical situations because it provides very useful information for diagnosis and is safe and inexpensive. In current practice, ultrasound produces only two-dimensional images, representing slices through the body. These can be quite difficult to interpret, and require the ultrasonographer to mentally integrate the information to form an image of the suspect area. Considerable skill is often required even to position the sensor so as to acquire a potentially useful image or combination of images.

If these difficulties could be addressed, ultrasound could provide a diagnostically valuable, low-cost imaging modality suitable for situations where a rapid diagnosis at a remote site is needed. Currently, the Army (through the ARPA Advanced Biomedical Technologies Initiative) is looking to develop a portable 3-D ultrasonic imaging system for use in diagnosing battlefield injuries. Our work is sponsored by that initiative.

Three-dimensional (3-D) ultrasound offers the potential to alleviate the problems addressed above. Because 3-D volumes show more context than 2-D slices, it becomes easier for users to understand spatial relationships and detect abnormal conditions. Positioning the sensor so as to acquire useful images is also easier with 3-D, because volumetric data can readily be rotated and realigned to good viewing positions, largely independent of the original sensor position.

In order to make 3-D ultrasound a practical reality, however, improvements are required in two areas. The first area requiring improvement is 3-D ultrasound image acquisition. One approach is to mechanically scan the sensor head of a conventional ultrasound unit, perpendicular to its imaging plane, so as to produce a sequence of conventional B-scan images. The sequence is then treated as a 3-D image. This approach is reasonably easy and effective, but suffers from long image acquisition time (seconds)

and from relatively poor focus along one axis due to the thickness of the ultrasound beam. A second approach is to use 2-D arrays of unfocused transducers, combined with holographic or synthetic aperture reconstruction techniques. This approach potentially offers both rapid image acquisition and excellent resolution on all axes, but requires a high computational rate in order to run in real time. At this time, ultrasonic holographic array technology is only at the proof-of-principle stage. Both approaches are being pursued by an ARPA-funded research project currently underway as a collaboration between Battelle and Madigan Army Medical Center.

The second area requiring improvement is 3-D volumetric display. Ultrasound presents some difficulties that are not found in other 3-D imaging modalities such as CT and MRI. Foremost among these are that 1) ultrasound images are typically quite "cluttered", with significant backscatter and intensity variations occurring throughout tissue volumes, and that 2) because of image aperture limitations and because ultrasound is inherently directional, the apparent brightness of tissues and interfaces depends on their position and orientation. Combined, these two aspects make it extremely difficult to explicitly reconstruct anatomically correct 3-D surfaces from ultrasound images. This is a sharp contrast to CT and MRI, where explicit surface reconstruction and display is often the method of choice. Thus, in dealing with 3-D ultrasound, we are faced with the dilemma that humans are not good at visualizing 3-D "clouds" of data, but that is exactly what the imaging process provides. An excellent article that presents the state of the art circa 1992 is found in [Bajura]. Our work aims to address two open-ended problems discussed in that work: visual cues and real-time volume visualization.

We have had good success in producing easily interpreted displays of 3-D ultrasound data through a unique combination of individually standard display techniques, including:

- stereo display (using a commercial LCD headset),
- real-time rotation and rocking,
- nonlinear intensity and opacity maps,
- a gradient-based lighting model, and simple shadows,
- all operating on the original 3-D volume (no explicit surface reconstruction).

The remainder of the paper is outlined as follows: in the next section, we provide a general introduction to volume visualization and discuss existing algorithms for visualizing 3-D medical data. Section 3 describes our experiences using volume rendering to visualize 3-D ultrasound data. The last section summarizes and discusses plans for future related work.

Volume Visualization

Volume visualization can be defined as a process that uses computer graphics to display structure contained in a three-dimensional dataset. This volumetric dataset can be thought of as a discretized function, F, over some bounded domain. The domain's topology varies from one application to another, but quite often is rectilinear:

$$F(X_i, Y_j, Z_k),\ i=1,N_x,\ j=1,N_y,\ k=1,N_z$$

This is a generalization of the "cuberille" model [Chen] where the spacings, dx,dy,dz, along the three orthogonal axes are equal. CT and MR data typically have equal spacing along intra-slice directions (dx=dy), but the distance (dz) between slices is often larger in order to minimize ionizing radiation exposure. Scanned ultrasound data often has the same format. The remainder of this section will be in the context of rectilinear volumetric scalar data.

There are currently two general techniques for visualizing volumetric data: surface rendering and volume or direct rendering. They are inherently different in both the underlying algorithms and the results produced. We provide an overview of the more popular algorithms in the remainder of this section.

The distinction in the results produced by the two techniques is that a surface renderer typically generates polygonal geometry, whereas a volume renderer generates an image. Because surface rendering preceded volume rendering in the genealogy of computer graphics algorithms, graphics workstations have evolved to be extremely fast polygon renderers. This, at least in part, accounts for the large collection of papers and software aimed at surface rendering. Volume rendering has become increasingly popular since the SIGGRAPH '88 publication of three papers on the subject [Sabella,Upson,Drebin]. There seems to be an ongoing debate as to whether surface rendering or volume rendering is superior. Little information is published that tries to make a comparison between the two [Udupa]. As we hinted in the Introduction, certain medical imaging modalities may lend themselves better to one visualization technique over another.

Probably the most prevalent algorithm to perform surface rendering on volumetric data is Marching Cubes [Lorensen]. This algorithm constructs a polygonal isosurface from rectilinear scalar data as follows:

- for each cube (voxel) consisting of eight vertices, determine the topology of the through that cube;
- using an enumerated case table of topologies, compute the geometry of the triangles the isosurface via some interpolant;
- for improved shading, compute the gradients at the cube vertices and then interpolate to obtain triangle vertex normals.

The SIGGRAPH '88 papers mentioned above offer a glimpse into the classification of volume rendering algorithms. The two broad classes are image-order and object-order. An image-order algorithm casts rays from image pixels into the volumetric data. For each voxel that a ray intersects, relevant information is accumulated to compose the final pixel value. An object-order algorithm operates on the volumetric data in memory-order and essentially projects ("splats") the voxels onto the image in either front-to-back or back-to-front order. The front-to-back method is essentially a volumetric Z-buffer algorithm. What these two classes of algorithms have in common is the basic functionality of mapping the scalar volumetric data, F, into both an intensity (color) function, I(F(x,y,z)), and an opacity function, O(F(x,y,z)). These are collectively known as transfer functions. Allowing a user to (interactively) modify these functions permits improved visualization of relevant structure(s) within the data.

Drebin et al presented an algorithm for transforming the shaded volumetric data into the viewing coordinate system to allow for a projection, via compositing [Porter], along an axis of the stored volume. This work was clarified and extended in [Hanrahan] which decomposed the viewing transformation into a sequence of three shearing matrices. A further improvement to this basic concept of aligning voxels (object space) with pixels (image space) is described in [Lacroute 94]. In this work, object space is mapped into a sheared object space which is ideally suited for projecting (compositing) into image space. Furthermore, the authors take advantage of spatial coherence by implementing scanline-based data structures in both object space and image space in order to speed up the rendering algorithm. Moreover, they offer three variants of the algorithm:

- render a fixed, preclassified volume, but with an arbitrary viewing transform and arbitrary shading parameters (fastest) {A classified volume is one that has an assigned to each voxel}

- render a fixed volume with an associated min-max octree; arbitrary classification, viewing transform, and shading (slower)

- render a fixed volume with no precomputed data structures (slowest).

An implementation of this algorithm is available via the Internet and is known as the VolPack library.

Another volume-rendering technique uses 3-D texture hardware to speed up the projection of object space to image space [Cabral,Cullip]. One such architecture capable of performing this is the Silicon Graphics RealityEngine. SGI provides an implementation of such an algorithm, known as Volren.

Results

We began our investigation with the visualization of ultrasound data from a breast phantom containing internal cysts. The data was obtained by another research group at Battelle using a holographic ultrasonic imaging technique [Sheen]. We were initially given a 512x512x128 dataset of floating point values and told that the data should be log scaled for better viewing. To make the data volume more manageable we first averaged each of the 128 slices to 256x256 resolution.

We wanted to first render this particular dataset using a volume rendering technique and therefore downloaded the Volren package. After converting our data into TIFF images, one of the required formats for Volren, we discovered that our machine had only enough texture memory to handle a 128x128x64 (or equivalent size) volume. We therefore averaged our 128 slices down to 128x128 resolution and then averaged pairs of slices to obtain a 128x128x64 volume. Figure 1 shows the resulting volume rendering as well as the Volren graphical user interface (GUI). We found Volren to be a very powerful tool for demonstrating the concept of volume rendering to others. The GUI allowed for interactive control of transfer functions that we did not expect to be possible at the beginning of our project. Combined with dynamic viewing (rotation and scaling), Volren provided us terrific initial results. However, with the demand for the SGI Onyx RealityEngine at a premium, we sought other avenues for visualizing our volumetric data.

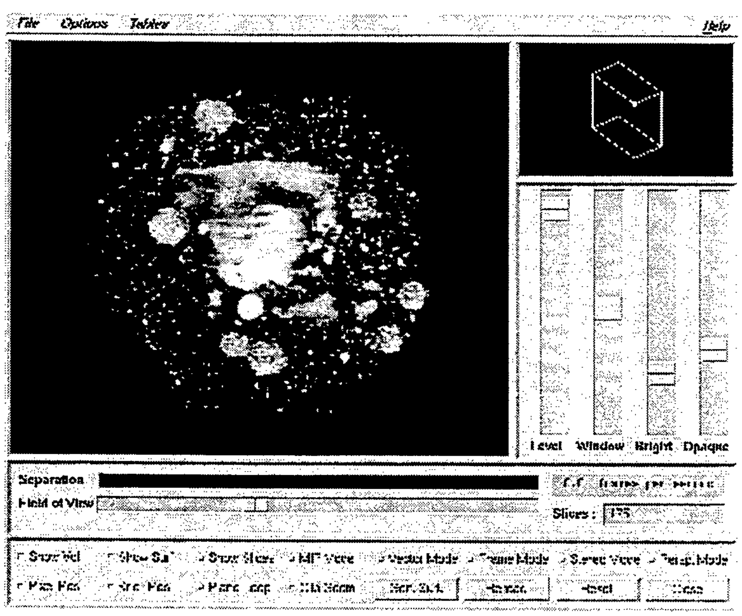


Figure 1. Breast phantom data rendered using Volren.

To satisfy our curiosity at how well a surface renderer would perform on this same data, we computed several isosurfaces of differing isovalues. Figure 2 shows one such surface that closely resembles the Volren rendering. (The isosurfaces were computed and rendered using the AVS visualization package.)

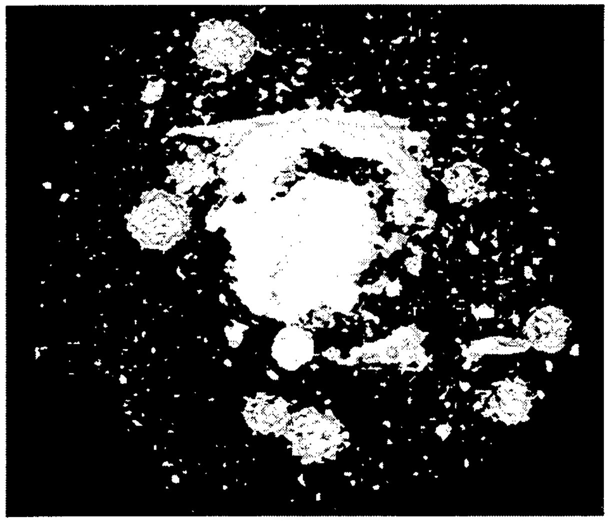


Figure 2. Isosurface of breast phantom data.

Next, we downloaded the VolPack (http://graphics.stanford.edu/software/volpack/) volume rendering library and began learning the mechanics of it. There is sufficient documentation in the form of a user's guide, man pages, and example datasets and programs. Though we were no longer bound by the texture memory limit, we kept the breast phantom data at 128x128x64 for comparison. Figure 3 shows an image rendered using VolPack with appropriately chosen transfer functions to approximate the Volren and isosurface renderings.

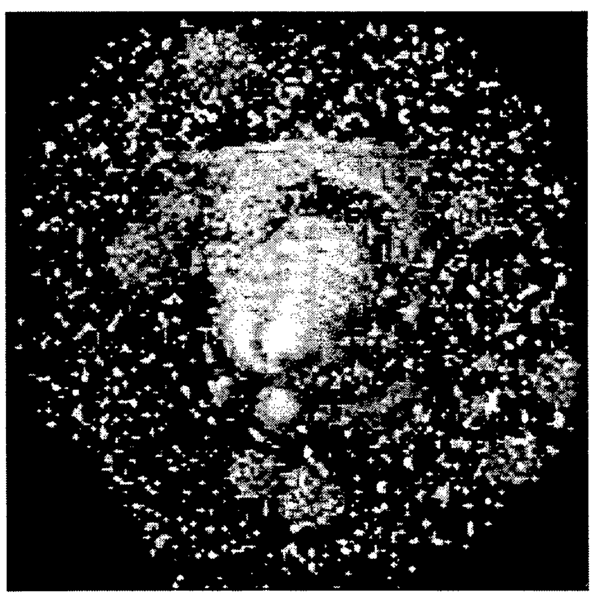


Figure 3. Volume rendering using VolPack.

Figure 4 (not shown) is the first frame in an MPEG animation showing a rotation of the breast data. These images were generated using the VolPack library. Note that depth-cueing is a user-specified option. [Note: Figure 4 is the same image as Figure 3.]

In Figure 5, we show a volume rendered image, using Volren, of the face of a fetus with a cleft palate. The data was taken with a conventional B-scan ultrasound imaging unit. The original volume consists of 50 slices at 190x236 resolution. Figure 6 is the first image of an MPEG animation generated using VolPack. Note the shadows which, in addition to the lighting model, serve as helpful 3-D visual cues. Here, we have chosen transfer functions that allow for deeper penetration of the facial skin in an attempt to visually reveal the cleft palate.

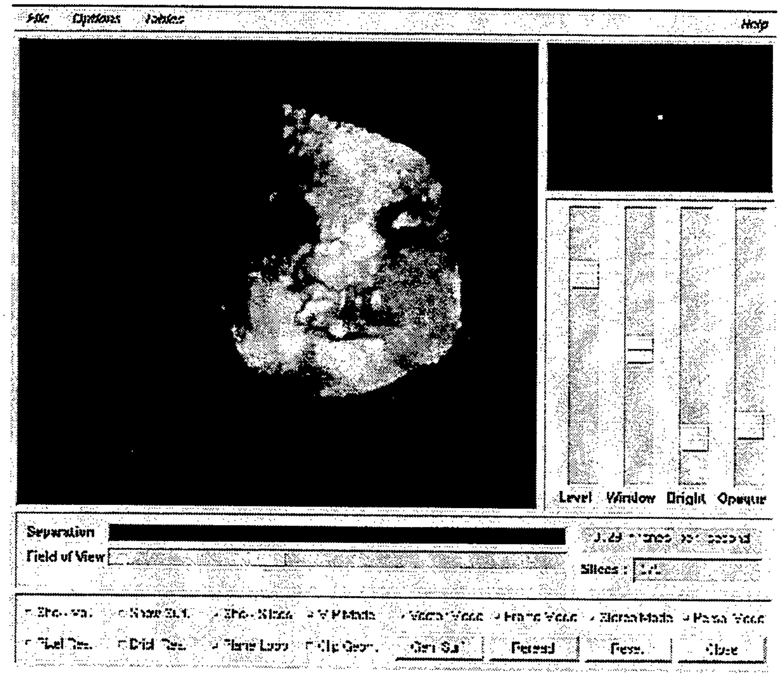


Figure 5. Volren on fetal face.

Figure 6. Fetal face (MPEG: 272K, 256x256)

Figure 7 shows the image from a volume rendering of another fetus dataset. Again the related MPEG animation was generated using VolPack and demonstrates its scaling and translation transformations.

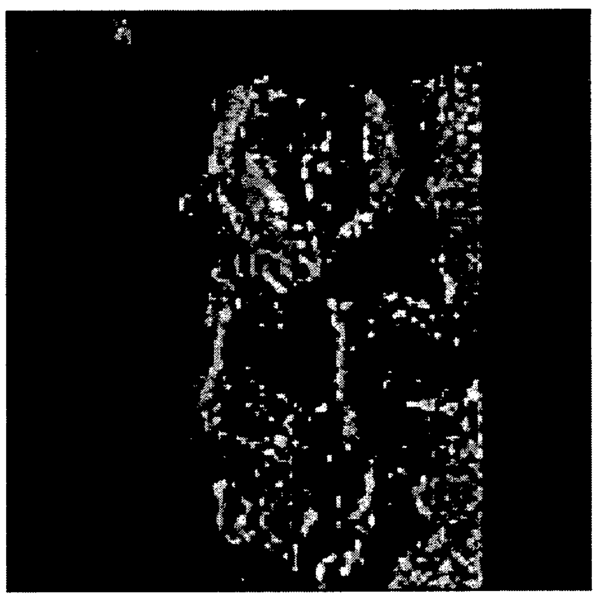


Figure 7. Fetus dataset (MPEG: 107K, 256x256)

One of our goals for this project was to provide stereoscopic displays of volume rendered images. Using the VolPack library, we generated left and right stereo pairs of images. From these we could provide either cross-eye stereo pairs or interlaced scanline stereo images which we viewed using the Virtual i/o i-glasses! (TM) shown in Figure 8.

Figure 8. The Virtual i.o i-glasses!

Figure 9 and Figure 10 (not shown) are MPEG rotations (fast and slow) of cross-eye stereo images. Figure 11 (not shown) is an MPEG rotation of interlaced scanline stereo images which can be properly viewed wearing a pair of i-glasses! (TM). [Note: Figure 10 is not shown since it is the same image as Figure 9. Figure 11, while possibly useful for viewing via a Web browser, is not shown in this paper document since it is a fuzzy image of little value without the proper viewing hardware.]

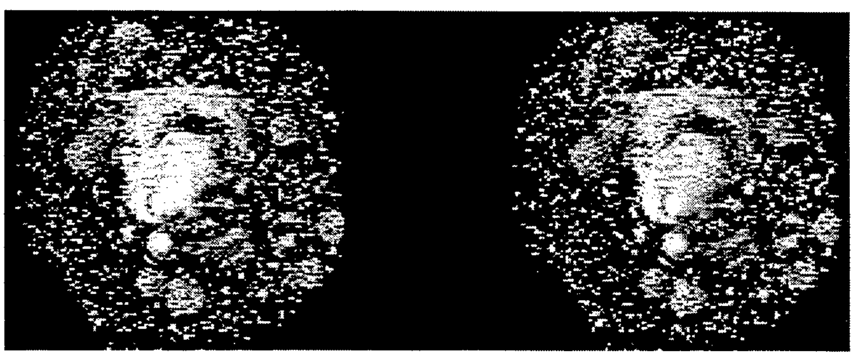


Figure 9. Cross-eye stereo of breast phantom.

In addition to visualizing ultrasound data, we also experimented with volume-rendering CT and MR data from the Visible Human Project (http://www.nlm.nih.gov/

extramural_research.dir/visible_human.html). Figure 12 shows a slice of CT data from the lower abdomen with clipping lines that we used to delimit a subregion around the spine. Extracting a volume of data in this fashion, we used the VolPack library to generate the images in Figures 13 and 14. Here we have chosen appropriate transfer functions to highlight the spine (bone) from the rest of the tissue.

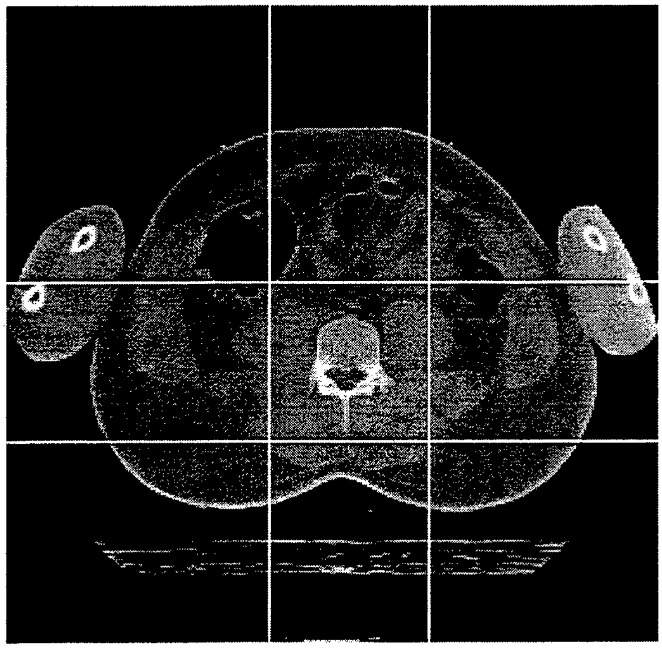


Figure 12. CT slice with clipping lines.

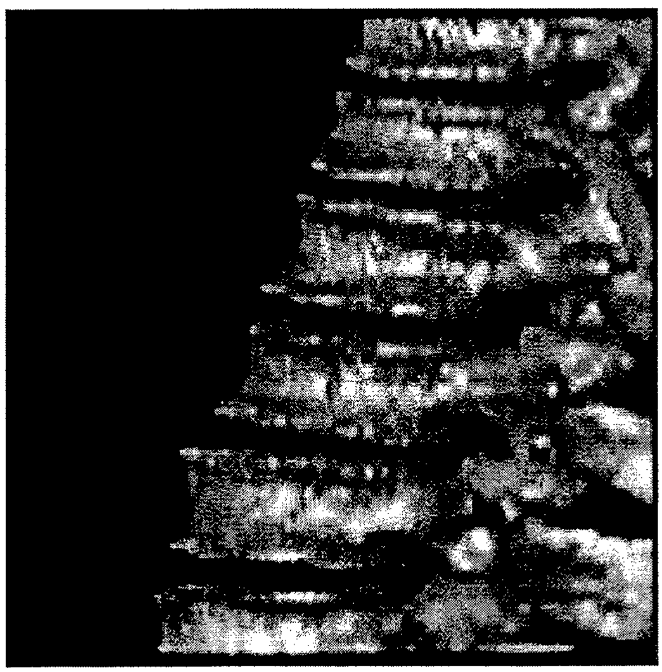


Figure 13. Lower spine from CT data.

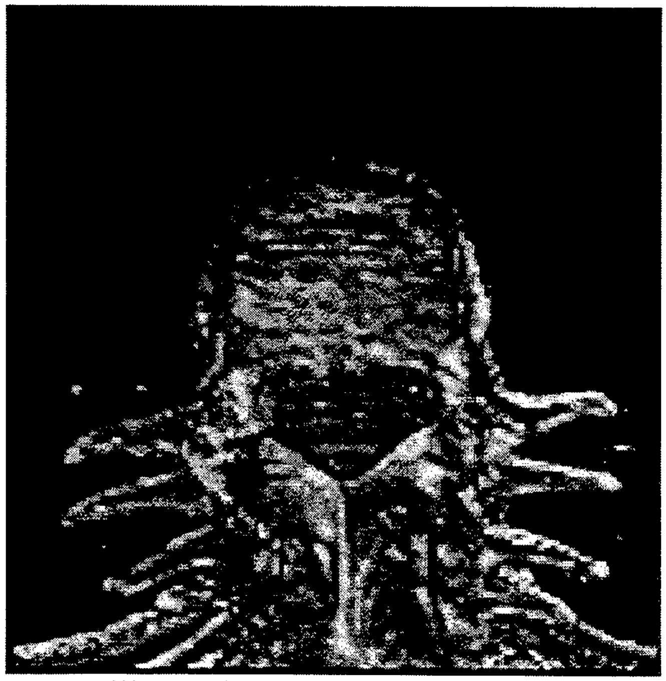


Figure 14. Another view of the spine.

Future Work

In a related project at Battelle, we are investigating extensions to the work described here. We have embedded the stereographic volume-rendering into an immersive virtual environment that allows a user to interactively view and perform simple editing of the volumetric data [Heiland].

We are in the process of porting the VolPack library and our stereographic image application to a Macintosh PowerPC as an extension to the NIH Image application.

Finally, we plan to incorporate and experiment with a parallel version of VolPack when it becomes available [Lacroute 95].

Acknowledgments

This work was supported by funds from the Advanced Research Projects Agency (ARPA), contract number DAMD17-94-C-4127. Initial research in volume visualization was funded by a Laboratory Directed Research and Development (LDRD) project through the Environmental Molecular Sciences Laboratory (EMSL) at Pacific Northwest National Laboratory. Additional support was through a LDRD project in the Medical Technologies and Systems Initiative at Pacific Northwest National Laboratory. Pacific Northwest National Laboratory is a multiprogram national laboratory operated by Battelle for the U.S. Department of Energy under Contract DE-AC06-76RLO 1830. The National Library of Medicine and the Visible Human Project provided CT and MR data. Finally, we would like to thank the following individuals: Dr. Rick Satava, our project manager at ARPA, for his consistent encouragement; Phil Lacroute for timely replies to questions about VolPack; Todd Kulick and Brian Cabral for answering questions about Volren; and our colleagues Dale Collins, Dave Sheen, and Parks Gribble for providing holographic ultrasound data.

References

Bajura M, Fuchs H, and Ohbuchi R. 1992. "Merging virtual objects with the real world: Seeing ultrasound images." SIGGRAPH '92 Conference Proceedings in *Computer Graphics* 26(2):203-210.

Cabral B, Cam N, and Foran J. 1995. "Accelerated Volume Rendering and Tomographic Reconstruction Using Texture Mapping Hardware." SIGGRAPH '95 Conference Proceedings in *Computer Graphics Annual Conference Series 1995*, pp. 91-98.

Chen LS, Herman GT, Reynolds RA, and Udupa JK. 1985. "Surface Shading in the Cuberille Environment." *IEEE Computer Graphics and Applications*, December 1985: 33-43.

Cullip TJ and Neumann U. *Accelerating Volume Reconstruction with 3D Texture Hardware*. Tech Report TR93-0027, Univ of North Carolina, Chapel Hill.

Drebin RA, Carpenter L, and Hanrahan P. 1988. "Volume Rendering." SIGGRAPH '88 Conference Proceedings in *Computer Graphics* 22(4):65-74.

Hanrahan P. 1990. "Three-Pass Affine Transforms for Volume Rendering." Proceedings of Workshop on Volume Visualization 1990 in *Computer Graphics* 24(5):71-78.

Heiland RW, May RA, Mauceri S. *A Low-Cost Immersive Virtual Environment for Volume Visualization*. In preparation.

Lacroute P and Levoy M. 1994. "Fast Volume Rendering Using a Shear-Warp Factorization of the Viewing Transformation." In SIGGRAPH '94 Conference Proceedings in *Computer Graphics, Annual Conference Series 1994*, pp. 451-458. (Web page http://www-graphics.stanford.edu/papers/shear/)

Lacroute P. 1995. "Real-Time Volume Rendering on Shared Memory Multiprocessors Using the Shear-Warp Factorization." To appear in Proceedings of the 1995 Parallel Rendering Symposium.

Levoy, M. 1988. "Display of Surfaces from Volume Data." *IEEE Computer Graphics and Applications* 8(3):29-37, 1988.

Lorensen WE and Cline HE. 1987. "Marching cubes: A high resolution 3D surface construction algorithm." SIGGRAPH '87 Conference Proceedings in *Computer Graphics* 21(4):163-169.

Neumann U. 1993. *Volume Reconstruction and Parallel Rendering Algorithms: A Comparative Analysis*. Ph.D. Dissertation, University of North Carolina - Chapel Hill.

Porter T and Duff T. 1984. "Compositing digital images." SIGGRAPH '84 Conference Proceedings in *Computer Graphics* 18(3):253-259.

Sabella P. 1998. "A Rendering Algorithm for Visualizing 3D Scalar Fields." SIGGRAPH '88 Conference Proceedings in *Computer Graphics* 22(4):51-58.

Sheen DM, Collins HD, and Gribble RP. 1996. "Ultra-Wideband Holographic 3-D Ultrasonic Imaging of Breast and Liver Phantoms." In Proceedings of Medicine Meets Virtual Reality: 4 (these proceedings).

Udupa JK and Hung HM. 1990. "Surface versus volume rendering: A comparative assessment." In *Proceedings of the First Conference on Visualization in Biomedical Computing*. Atlanta, Georgia. May 22-25, 1990.

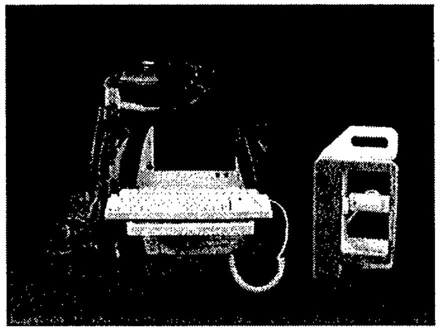
Upson C and Keeler M. 1988. "V_BUFFER: Visible Volume Rendering." SIGGRAPH '88 Conference Proceedings in *Computer Graphics* 22(4):59-64.

APPENDIX C

Appendix C: ***Presentation of the Prototype Advanced IMaging System (AIMS) at AUSA'95 (Association of the U.S. Army 1995 Annual Meeting, Washington, DC, October 1995).***

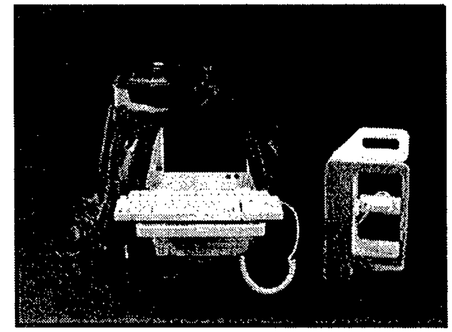
AIMS Testbed System

- Sequential B-scan technology
- Off-the-shelf components
- 60-pound backpack configuration
- Fully functioning modular prototype



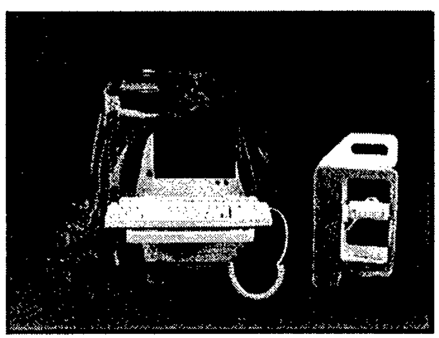
AIMS Testbed System

- Static 3-D Image Acquisition (10 seconds)
- Animated 3-D Volumetric Visualization (1-3 minutes generation time)



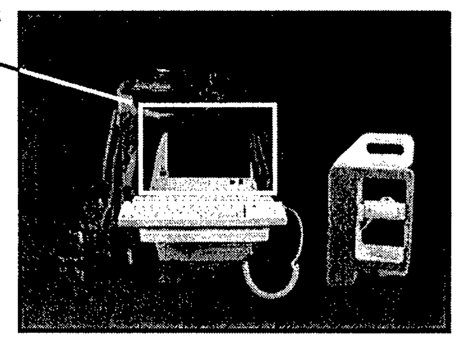
AIMS Testbed System Major Components

- Hitachi EU-405BPLUS ultrasound engine
- Transducer probe
- 1-axis mechanical scanner ("paddle")
- PowerMacintosh 7100 computer
- Virtual i-O stereovision headset



AIMS Testbed System Major Components

- Hitachi EU-405BPLUS ultrasound engine
- Transducer probe
- 1-axis mechanical scanner ("paddle")
- PowerMacintosh 7100 computer
- Virtual i-O stereovision headset



AIMS Testbed System Major Components

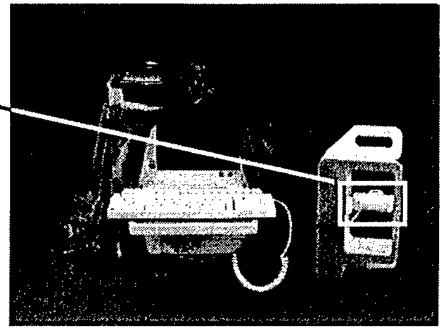
Hitachi EU-405BPLUS ultrasound engine

Transducer probe

1-axis mechanical scanner ("paddle")

PowerMacintosh 7100 computer

Virtual i-O stereovision headset



Appendix C Slide 5

AIMS Testbed System Major Components

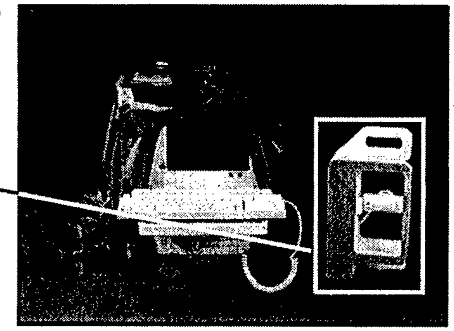
Hitachi EU-405BPLUS ultrasound engine

Transducer probe

1-axis mechanical scanner ("paddle")

PowerMacintosh 7100 computer

Virtual i-O stereovision headset



Appendix C Slide 6

AIMS Testbed System Major Components

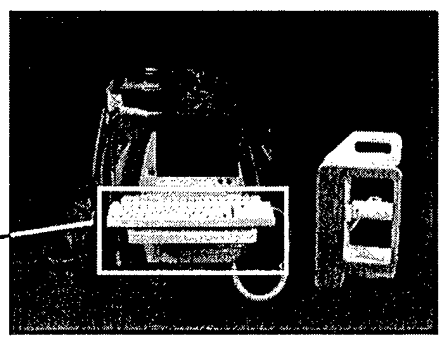
Hitachi EU-405BPLUS ultrasound engine

Transducer probe

1-axis mechanical scanner ("paddle")

PowerMacintosh 7100 computer

Virtual i-O stereovision headset



Appendix C Slide 7

AIMS Testbed System Major Components

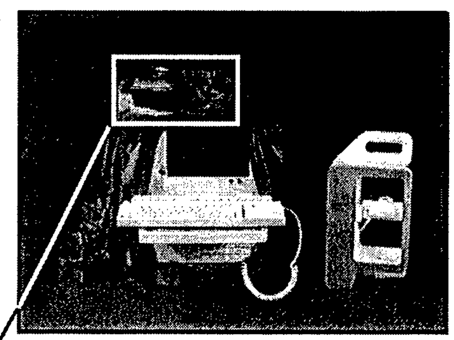
Hitachi EU-405BPLUS ultrasound engine

Transducer probe

1-axis mechanical scanner ("paddle")

PowerMacintosh 7100 computer

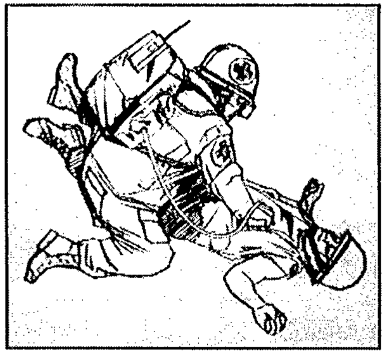
Virtual i-O stereovision headset



Appendix C Slide 8

AIMS Future-Generation Systems

- Real-Time Speed
- Lightweight, Monolithic 2-D Array Transducer
- Computational Holography Image Reconstruction



AIMS Partnership

- ARPA Biomedical Technologies Program
- Battelle Pacific Northwest Laboratories
- Madigan Army Medical Center

APPENDIX D

Appendix D: ***"Evaluation of 3-D Ultrasound Holographic Imaging at 1 MHz for Detection and Visualization of Abdominal Blood Pooling Using a Mechanically Scanned Single Channel Transducer and Laboratory Phantoms", submitted as Appendix 2 of the 1996 Annual Project Report.***

Appendix D: Evaluation of 3-D Ultrasound Holographic Imaging at 1MHz for Detection and Visualization of Abdominal Blood Pooling Using a Mechanically Scanned Single Channel Transducer and Laboratory Phantoms

(Phase 1, Task 2, report date April 25, 1996)

Task Description

Task 2 is the preliminary experimental evaluation of 1 MHz blood pool images on phantoms, etc., using holographic single channel and "1-D" array systems mechanically scanned at PNNL's Richland facility in the EDL laboratory.

The single channel system will be implemented to experimentally verify the viability of using 1 MHz ultrasound in the detection and imaging of blood pool phantoms before building the first test sub-array at 1 MHz.

The medical trauma community (as reported by Dr. Steven Doctor, PNNL scientist) has successfully used higher frequency (3 to 5 MHz) commercial B-Scanners to detect and image blood pooling in trauma patients. They indicate easy detection at these frequencies using present commercial B-Scanners. Typically, only one day is spent training for blood pooling which indicates it is a simple test with a commercial B-Scanner.

Our task is to evaluate the efficacy of using 1 MHz in the detection and imaging of blood pooling and using this information to construct a "2-D" array capable of "3-D" imaging for a portable combat field system. The decision to use the lower frequency is driven by the complexity and cost of building a high frequency "2-D" transmit / receive array that can be used in the combat "3-D" imaging field system. A simple 32 by 32 array (~5cm by 5cm) at 1 MHz using one wave length element requires 1024 transmit / receive channels for serial switching and many more if parallel and serial switching schemes are used for imaging in real time. The same size array at 3 MHz would require approximately 100 by 100 elements and 10,000 transmit / receive serial switching channels, etc. The higher frequency system would also have greater attenuation and with small transmit elements (with their inability to transmit high power) will decrease depth penetration in blood pool imaging. There are many complex engineering problems to consider when building a high frequency "2-D" transmit / receive array with present day technology. The design and fabrication of a viable "2-D" imaging array has challenged some of the best companies and universities in the United States, Europe and Japan and none exist today in commercial medical equipment.

PNNL will construct a phantom based on information from the medical community, image at 1 MHz using our holographic single channel system, and compare the images with a commercial B-Scanner (3.5 MHz).

The phantom will consist of simple foam (stomach layer) and duct putty (intestines) immersed in water with cavities between the foam and duct putty that simulate blood pools. This assumes the combat casualty is lying on his or her back and the blood rises above the intestines and is trapped by the thick muscle layer (stomach).

Holographic array images (1 MHz) will be integrated into "3-D" volumetric blood pool images for preliminary evaluation of simulated "2-D" array imaging with scanned "1-

D" data. These data will simulate the results expected with the "2-D" array that will be used in the battlefield system.

ARPA and expert medical staff will be able to view the single channel phantom blood pool images and determine the viability of using 1 MHz ultrasound for the battlefield "2-D" array blood pool imaging system. If the image resolution (blood pool phantoms) is found insufficient for battlefield diagnostics, PNNL will (with the approval of ARPA) proceed to a higher frequency (~2 MHz), design and fabricate the system. The design will follow along the higher frequency route with the appropriate changes, etc. If the resolution is sufficient at 1 MHz, we will proceed with design and fabrication of the "1-D" array and the "2-D" array combat system.

The small sub-array (few elements) will be designed and fabricated for imaging the blood pool phantom and comparing it with the single channel data. Single channel scanned data, using a one wave length transducer, is the optimum configuration for high resolution imaging and is used as the "gold standard" for comparing array data. The array, with its many elements closely packed together, has various cross-talk and acoustic coupling paths which tend to degrade the image quality as compared with a single channel system. After successful single channel tests at 1 MHz the "1-D", array will be designed and fabricated for testing.

The proposed "1-D", array will consist of 32 elements spaced one wave length apart, approximately 5cm in length. The width of each element is one wave length resulting in a 180 degrees main beam. After design and fabrication of the "1-D" linear array, tests will be conducted using the medical blood pool phantom and the results will be compared with the sub-array data. The results should be comparable if the sub-array data is acceptable for blood pool imaging at 1 MHz.

The "1-D" array when scanned in one direction with the x-y mechanical scanner, (generating many lines of data) will simulate a "2-D" array in non-real time. These tests will be conducted to provide simulated "2-D" array blood pool imaging data for the design of the this array in the next phase. The "2-D" array is the heart of the portable combat real time blood pool imaging system that will be carried by the field medic and used in diagnostic battlefield trauma.

B-Scan (Hitachi) Simulated Blood Pool Imaging of Phantom at 3.5 MHz

A blood pool phantom was constructed of multiple layers of foam (same type as used in the filter of a Tektronix scope fan) and duct putty inserted in a plastic bag (see figure 1). The use of foam was suggested by Dr. Jonathan Ophir, University of Texas medical school who is engaged in research dealing with emergency room trauma using ultrasound as a diagnostic tool for blood pooling. His wife, Karen Ophir, is a registered diagnostic sonographer and also teaches courses in emergency room trauma. Typically, only one day is spent training for detection of blood pooling in trauma patients. The detection is relatively simple using a B-Scan sector array operating above 2 MHz.

A Hitachi portable B-Scan with a 3.5 MHz linear (sector) array was used to image simulated blood pooling using the phantom shown in figure 1. If internal injury severs a large vein or artery in the abdomen, the blood rises (assuming the patient is on his back) upward toward the surface of his stomach and is trapped between the intestines and muscles of the stomach. The blood then forces the upper layer (1.3cm foam) to slightly bulge and form pockets between the intestines and the upper layer.

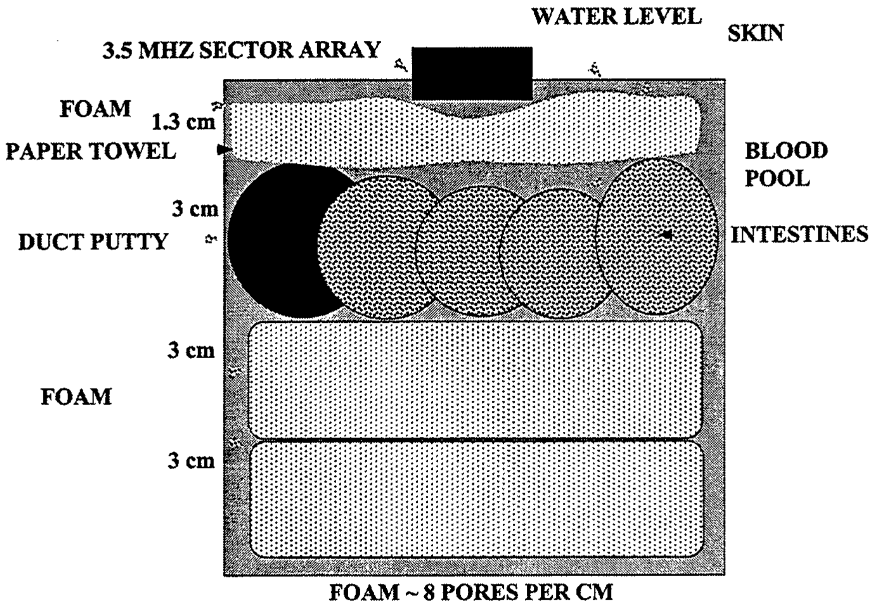
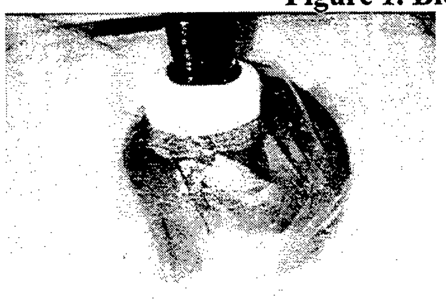
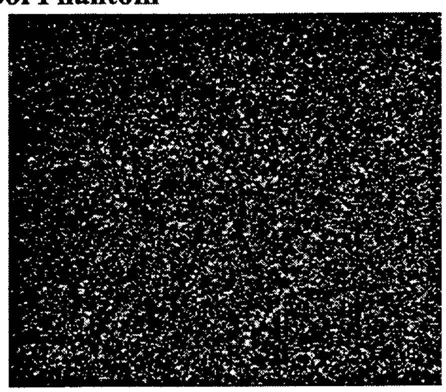


Figure 1. Blood Pool Phantom



(a)



(b)

Figure 2. Photographs of Duct Putty and Foam Used in the Phantom

Figure 2(a) shows the sector array above the duct putty (in plastic container) and (b) a top view of the black colored foam (~ 8 pores per cm) that was used in constructing the blood pool phantom as shown in figure 1. The foam is very coarse and the large pores can be seen in the photograph.

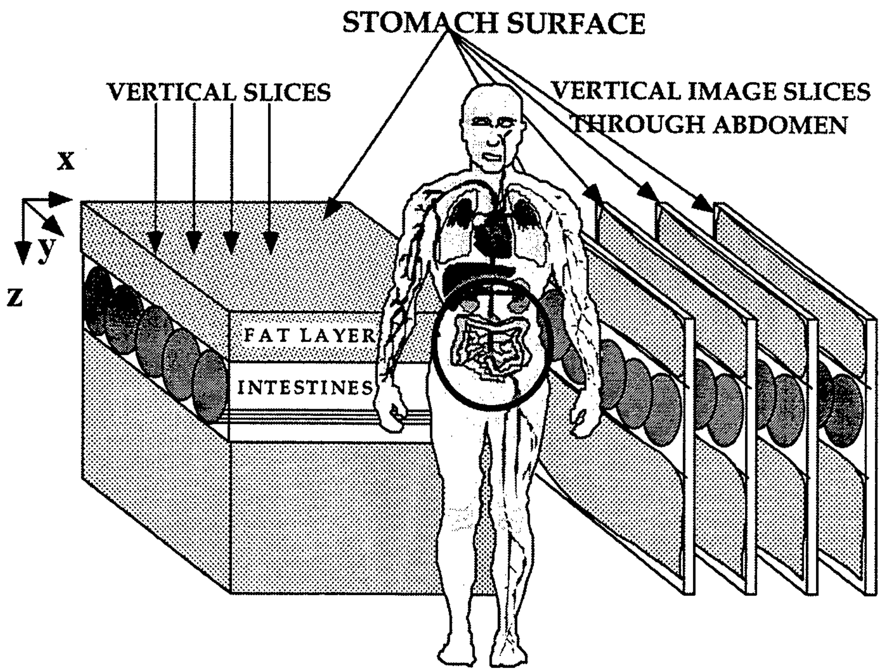


Figure 3. Blood Pool Phantom Slice Image Geometry

Figure 3 is a simple graphical illustration of the image display used in constructing vertical slice images (B-Scans) of blood pool phantoms and humans. The images are as if one cut vertical slices through the phantom (human) and then viewed them as a side view (YZ or XZ planes).

Figure 4 is a B-Scan image of the phantom with a single blood pool pocket as shown by the dark area between the intestines and the upper layer. It is easily seen with the high frequency sector array at 3.5 MHz. The intestines appear as the curved bright lines and entrapped gas in the bowels reflects the ultrasound leaving the dark area below the intestines void of sound waves.

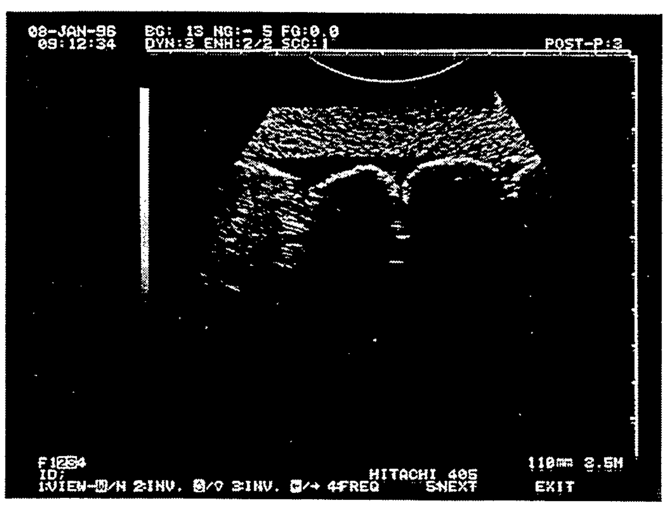


Figure 4. B-Scan Image of Blood Pool Phantom (3.5 MHz)

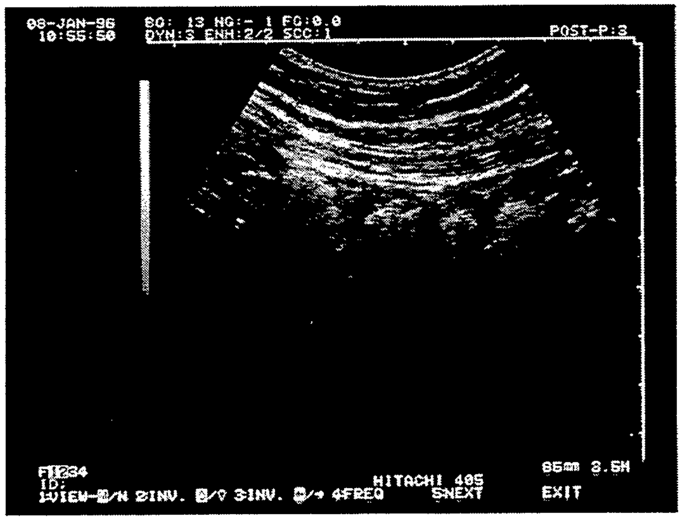


Figure 5. B-Scan Image of Normal (200 LB) Human (3.5 MHz)

Figure 5 is a B-Scan image of the stomach area of a normal (200 lbs) male for comparison with the blood pool phantom image. The dark area or pocket between the intestines and upper layer is absent (no blood pooling). The phantom image appears to be a relatively good model (scattering, etc.) with the insitu image at 3.5 MHz. The actual intestines appear curved in the human as simulated with the duct putty in a plastic container with entrapped air. The layers of muscle between the stomach and the intestines exhibit bright broken lines in the human and uniform scattering in the phantom. These lines can be simulated in the phantom by the insertion of thin paper towels with entrapped air. The phantom was altered and the results were very promising showing similar bright broken lines in the muscle.
There are a few dark areas above the intestines in the normal (200 LB) human (Figure 5), but they appear to have scattering centers within them indicating they are not filled with non-echo-genic blood.

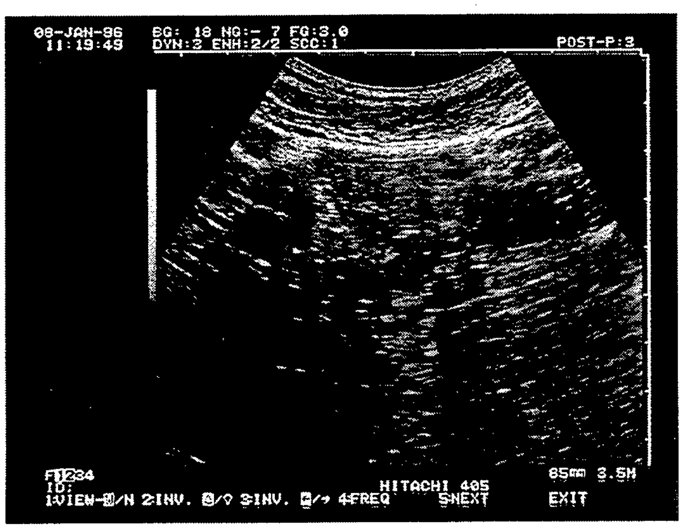


Figure 6. B-Scan Image of Normal (150 LB) Human (3.5 Mhz

Figure 6 is the B-Scan image of the stomach area of a normal (150 LB) human in good physical condition (very low fat content). The bright lines below the surface of the stomach are more concentrated than the 200 LB human and the area above the intestines has more scattering. The thickness of the fat or muscle layer is thinner on the 150 LB human indicating less fat within the layer.

Conclusion of Phantom Blood Pool Imaging (3.5 MHz) using a Commercial B-Scan with a Sector Array

Blood pool detection and imaging at 3.5 MHz is viable assuming the phantom is representative of a human in this condition. Information from the trauma medical community supports this conclusion and indicates that it is relatively easy to detect blood pooling using ultrasound above 2 MHz. Information of blood pooling detection and imaging using diagnostic ultrasound below 2 MHz appears to be unavailable. We believe the lack of data around 1 MHz is that no commercial B-Scans operate at frequencies below 2 MHz.

If the Army's combat portable "3-D" holographic blood pooling system is to be constructed at 1 MHz, then experimental imaging data should support the decision to reduce the "2-D" array's complexity and cost while retaining sufficient lateral resolution for imaging. The 1 MHz array frequency percent bandwidth should remain approximately the same as the higher frequency systems to insure adequate depth resolution.

Blood pool imaging data must then be collected using a laboratory 1 MHz imaging system to verify that sufficient scattering from the stomach layer muscles and upper surfaces of the intestines will provide acceptable resolution for blood pool imaging.

Single Channel 1 MHz Holographic "1-D" Imaging of Blood Pool Phantoms

A laboratory single channel rectilinear scanned 1 MHz holographic imaging system was configured to image blood pool phantoms. The tests were implemented to verify or refute the viability of using 1 MHz ultrasound in the combat field system employing a small "2-D" array.

The blood pool phantom used in the 3.5 MHz tests with the commercial portable B-scanner was set up in the laboratory water tank for single channel 1 MHz imaging using a focused transducer and the x-y scanner. Figure 7 is a simple cross sectional diagram of the foam duct putty blood pool phantom with a focused transducer above it in the water tank. The blood pool is simulated by water pocket between the upper layer foam (muscle layer) and the duct putty (intestines). The water pocket is non-echo genic and appears in the ultrasound image as a dark area.

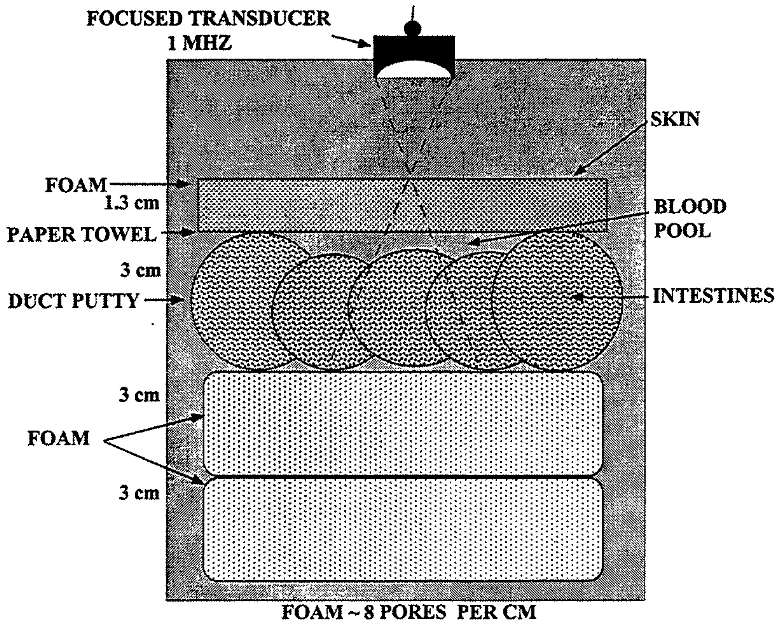


Figure 7. Blood Pool Phantom in water tank for 1 MHz Imaging Tests

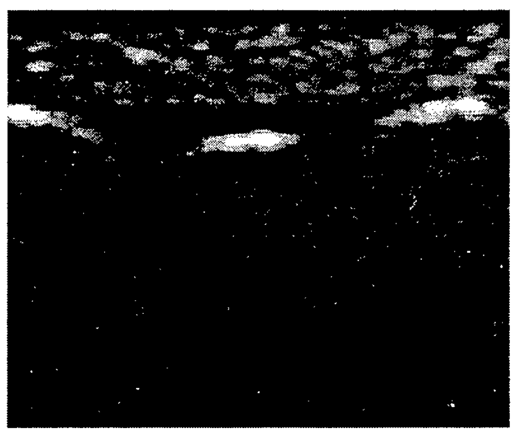


Figure 8. Holographic "1-D" Line Image of Blood Pool Phantom (1 MHz)

Figure 8 is a holographic (B-Scan) image (~ 7.5 cm in length and depth) of the phantom with a blood pool pocket as shown by the dark area between the intestines and the upper layer. The sample density is 0.5mm in the horizontal and 0.3mm in the vertical. It is easily seen at 1 MHz using the scanned holographic system using the focused transducer . The intestines appear as the bright areas (high reflectivity) as a result of entrapped gas in the bowels. The low frequency appears to penetrate around the air entrapped areas of the intestines and reflect from the lower foam layers. The high frequency B-Scan images show dark areas below the intestines indicating loss of ultrasound as a result of higher attenuation at these frequencies.

Single Channel 1 MHz Holographic "1-D" Imaging of Phantom (Normal)

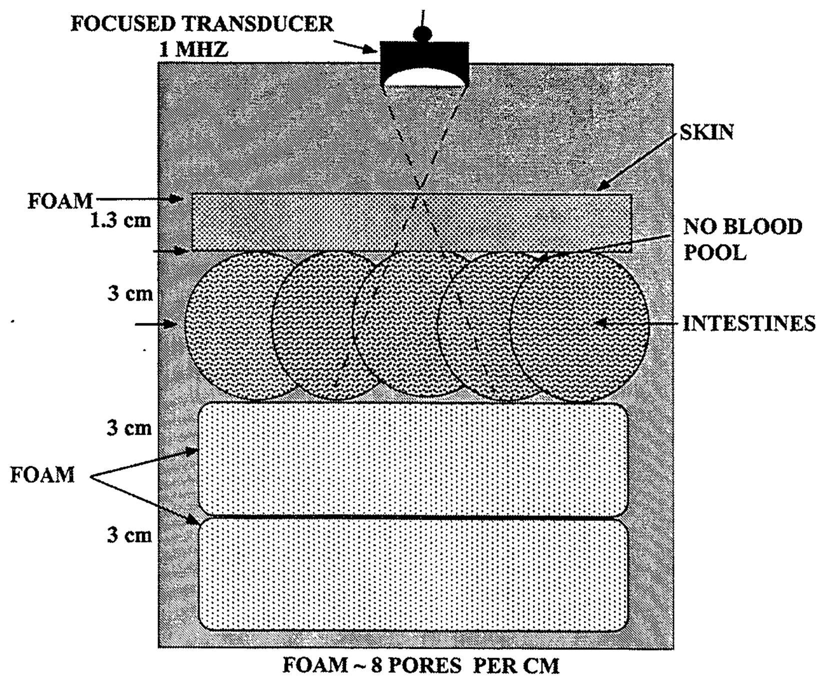


Figure 9. Phantom (No Blood Pool) in water tank for 1 MHz Imaging Tests

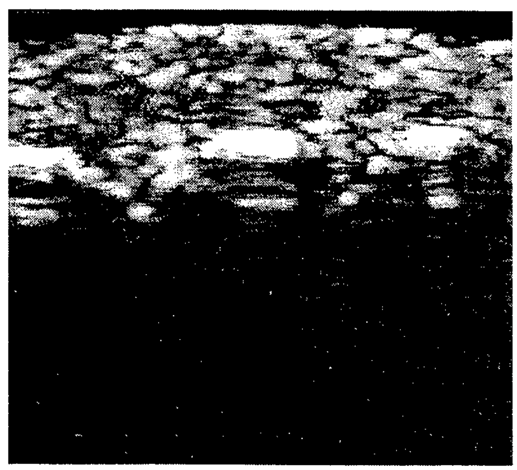


Figure 10. Holographic "1-D" Images of No Blood Pool Phantom (1 MHz)

Figure 9 is the geometry of the ultrasound phantom without blood pooling used in 1 MHz holographic imaging experiments. The phantom is essentially identical to the one used that simulated blood pooling, but without the water cavity between the upper stomach layer and the intestines.

Figure 10 is a holographic (B-Scan) of the no-blood pool phantom (7.5cm length and depth). The sample density is 0.5mm in the horizontal and 0.3mm in the vertical. The 1 MHz image shows the absence of very dark areas (compare with figures 7 & 8) between the stomach muscle layer (upper layer) and the intestines indicating no trauma from internal bleeding in this area. The dark areas below the intestines indicate that the ultrasonic energy is highly attenuated as a result of entrapped air in the intestines. Dark

areas in the images either indicate non-echo genic layers or loss of ultrasound from highly attenuative layers above these regions. To interpret the images correctly one must know where the source position of the ultrasound beam with respect to the x,y,z coordinates.

Comparison of Image Resolution Between Commercial B-Scan (3.5 MHz) and Holographic (1 MHz)

Figure 11 is a composite collection of commercial B-Scan (Hitachi 3.5 MHz) and holographic images (1 MHz) of a blood pool phantom and human for comparing lateral and depth resolutions. Figure 11(a) is a B-Scan image of the blood pool phantom with the dark area (blood pool) between the upper fat or muscle layer and the intestines (curved lines). Figures 11(b)is the 1 MHz holographic image of the blood pool phantom. The lateral resolution at 1 MHz is obviously less than the three focal zone B-Scanner at 3.5 MHz. The dark area (blood pool) in the holographic image (11b) is easily identified and imaged at
1 MHz.

Figure 11(c) is the B-Scan image (3.5 MHz) of a 200 LB normal human (stomach area) showing bright lines interlaced in the muscle layer and the characteristic scallop lines (intestines) below them.

Figure 11(d) is the 1 MHz holographic image of a phantom without blood pooling. The dark area between the stomach layer and intestines is absent indicating no trauma from blood pooling. We assume that a combat wound (internal bleeding) in this area would give rise to significant bleeding in this cavity, and would be easily identified as compared withthe small cavities that were simulated in our phantom.

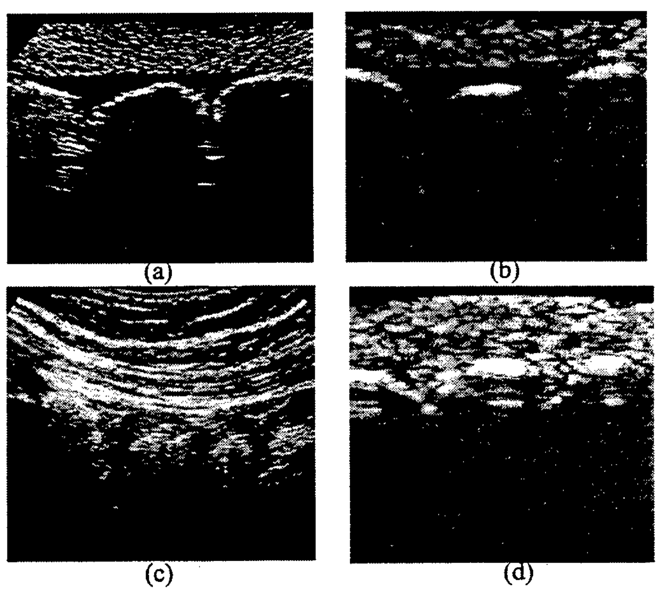
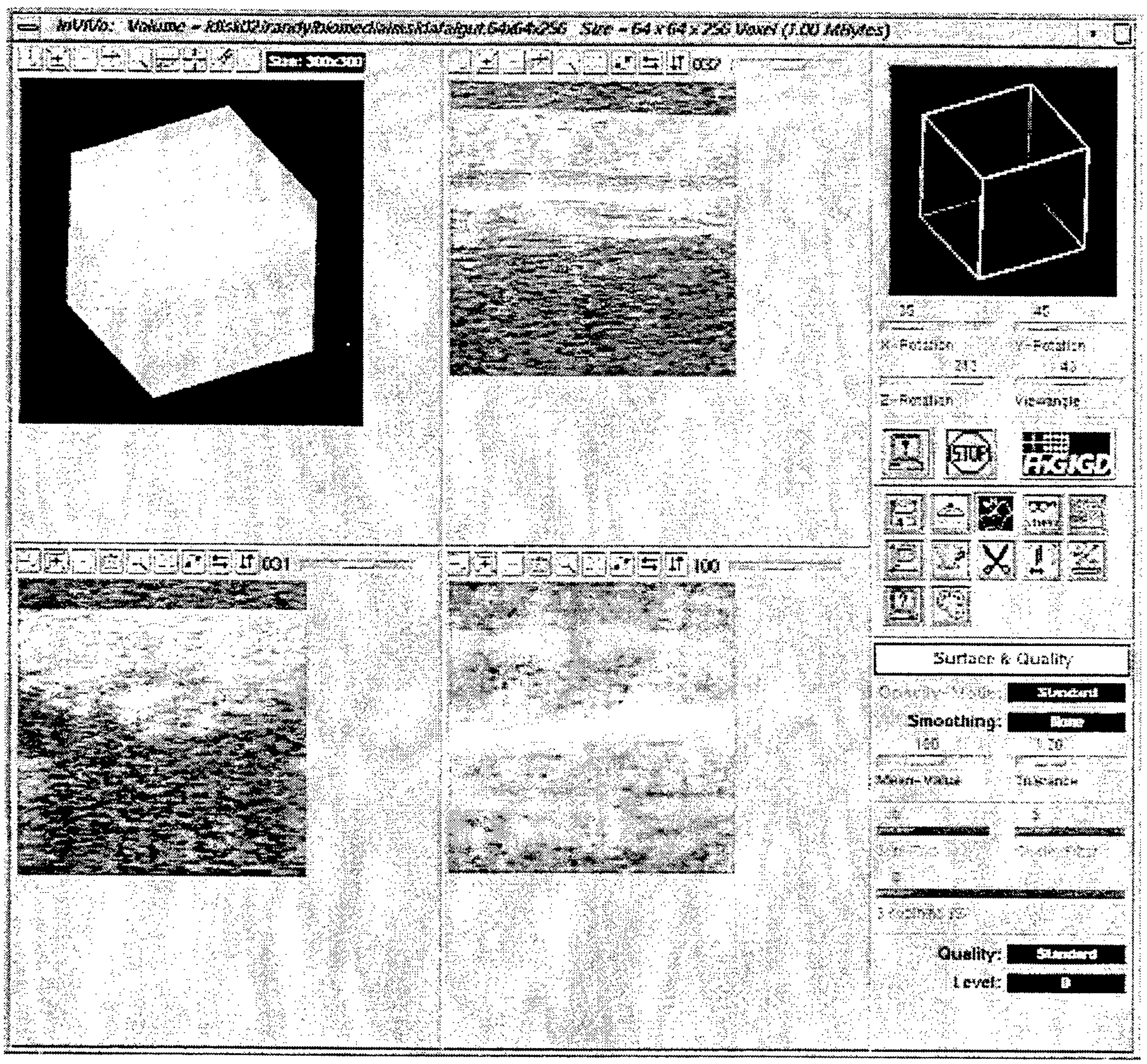


Figure 11. Comparison of B-Scan (3.5 MHz) and Holographic (1 MHz) Images of Blood Pool Phantoms and Human

3D Volumetric Visualization

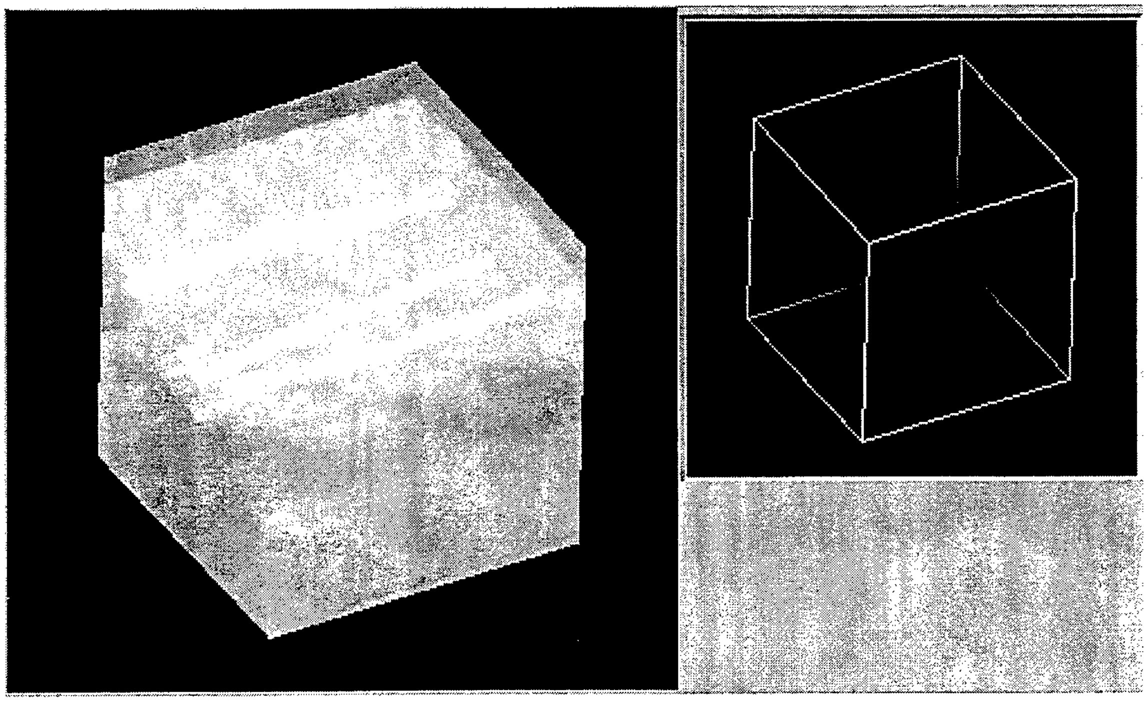
Figures 12 and 13 illustrate the fully three-dimensional nature of the holographic image datasets. Both figures show a 64x64x256 image (256 depth planes), obtained by a 1 MHz holographic scan, of a blood pool phantom consisting of 3 parallel sections of "intestine".
Figure 12 shows a full-screen view of the user interface provided by the InViVo software package [1]. A volumetric view of the entire data set, viewed obliquely, is shown in the upper left quadrant, with a wireframe representation of the viewing angle shown in the upper right inset. The other three quadrants (outlined in red) show 2-D views of the holographic dataset, resliced on the YZ, XZ, and XY orthogonal axes. (2-D slices at arbitrary angles can also be obtained, but this capability is not illustrated here.) Figure 13 shows full-size volumetric images of the dataset from two angles.

At present, it appears that the major value of volumetric visualization for blood pool detection is to provide a 3-D context within which to evaluate 2-D slice images. However, the ability to reconstruct (select) arbitrary 3-D slices from the holographic datasets should provide a powerful tool for interpretation.



[1] InViVo is a product of the Fraunhofer Center for Research in Computer Graphics, Providence, RI.

Figure 12. 3-D and orthogonal slice views of holographic images, as rendered by InViVo software package (full screen).



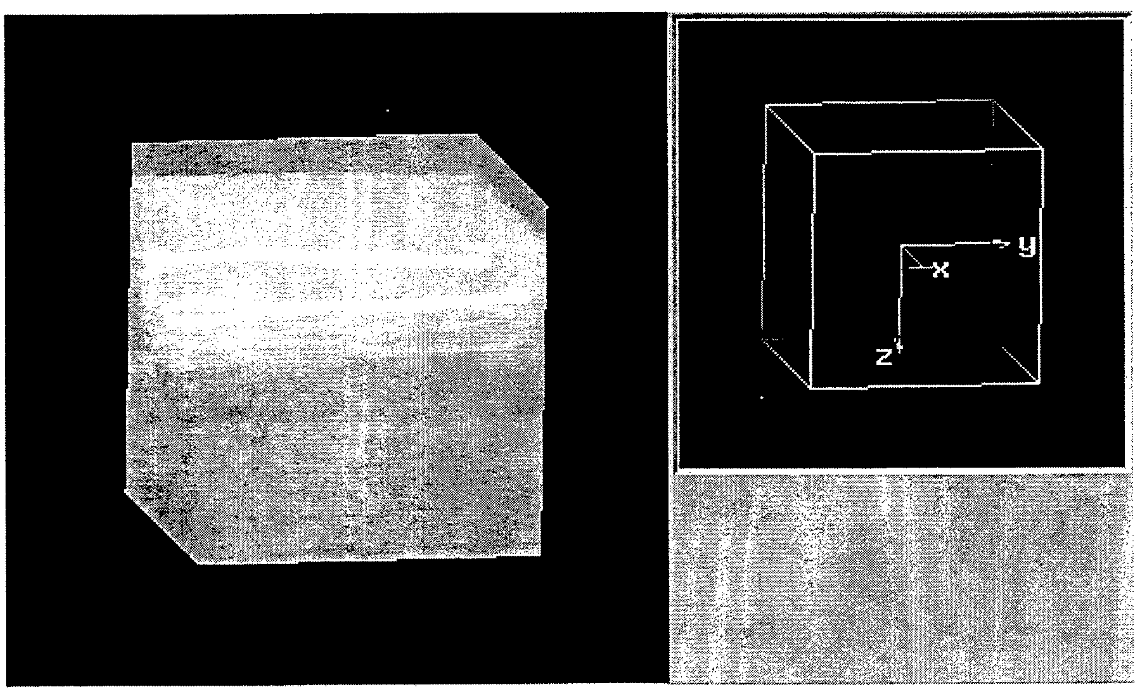


Figure 13. Volumetric views (Maximum Intensity Projection) of holographic images of the blood pool phantom.

Conclusion of Phantom Blood Pool Imaging (1 MHz) using PNNL's Holographic Imaging System

Blood pool detection and imaging at 1 MHz appears to be viable assuming the phantom is representative of a human in this condition. University of Texas medical staff working in the field of trauma gave PNNL directions for constructing a phantom similar to those they use in B-Scan training for blood pooling. On the assumption that the phantom is representative of the human body at 1 MHz, blood pooling is detectable and can be imaged at this frequency.

If the Army's combat portable "3-D" holographic blood pooling system is to be constructed at 1 MHz, sufficient experimental imaging data at 1 MHz should support this important decision. The next phase of this program (building the "2-D" array) depends on the successful results of 1 MHz blood pool imaging with the "1-D" array. The "2-D" array's complexity and cost would be significantly reduced if 1 MHz can be used.

APPENDIX E

Appendix E: ***Coherent Lens-Based Image Reconstruction, April 3, 1996, submitted as Appendix 3 of the 1996 Annual Project Report.***

Coherent Lens-based Image Reconstruction

D. M. Sheen

April 3, 1996

BATTELLE MEMORIAL INSTITUTE

PACIFIC NORTHWEST NATIONAL LABORATORY

PO Box 999

Richland, WA 99352

Abstract

This paper demonstrates how holographic, or Fourier optic, image reconstruction techniques may be applied to a lens-based coherent imaging system. These techniques overcome the limitations of lens-based systems such as limited resolution and very limited depth-of-field (or depth-of-focus). Additionally, these techniques are suitable for full three-dimensional high-resolution imaging.

1. Introduction

Efforts are presently under way to fabricate large-scale two-dimensional arrays for ultrasonic imaging applications. For example, one such system is being designed by Loral and will consist of a 2-D array of 128 by 128 elements. The element spacing is 200 μm, or two-thirds wavelength at the center frequency of 5 MHz Thus, the array will be approximately 25.6 mm square. Each element will allow quadrature detection (I and Q) of the scattered wavefront. The present design will use coherent external illumination sources. A lens (7 - 10 cm diameter) will be used to increase the image size (demagnify) so that the visible aperture is on the order of 7 - 10 cm. An additional advantage of the large lens is that it will capture the ultrasonic energy over a larger aperture than would imaging with the array without using a lens.

Efficient high-resolution imaging is possible using a 2-D array without using a lens at all. The sampled wavefront can be 'back-propagated,' using holographic (Fourier optic [1]) image reconstruction techniques to form the image that existed at the object plane. This image reconstruction technique utilizes the 2-D Fourier Transform to decompose the scattered wavefront into a number of discrete plane wave components. These plane wave components can then be phase-shifted (or back-propagated) to the object plane. The inverse Fourier Transform then yields the focused image. A larger effective image size can be obtained by artificially increasing the size of the data array by zero-padding. This type of image reconstruction has also been extended (at PNNL) to true three-dimensional imaging by utilizing coherent wide-bandwidth illumination. The I and Q waveforms can be digitized over a time interval and the time series can then be Fourier Transformed to yield the scattered wavefronts magnitude and phase over a wide frequency bandwidth. This data can then be back-propagated resulting in a fully focused 3-D image of the object.

Advantages of this type of synthetic processing are that no paraxial, Fresnel, or Fraunhofer approximations are made. Therefore, the target objects can be close to the array, and can fill the array aperture without significant degradation of the theoretical diffraction limited resolution. This resolution is approximately

$$\delta_{\text{lateral}} = \frac{\lambda}{2}\left(\frac{R}{L}\right) \tag{1}$$

$$\delta_{\text{depth}} = \frac{u}{2B} \tag{2}$$

where λ is the wavelength, R is the range to the target, L is the aperture size, u is the speed of wave propagation, and B is the bandwidth. Generally it is possible to achieve F-1 or F-2 for resolution of one-half to one wavelength, where F-n refers to the optical F-number or *R/L*.

However, there may be advantages in using a lens in this type of imaging system. The aperture over which the acoustic energy is gathered can be significantly larger than the array. This may lead to an enhanced signal-to-noise ratio. Also, a lens may be used effectively to magnify or demagnify the image size. The techniques shown in this paper may be used to essentially '*fine-tune*' the images obtained from a lens-based imaging system to obtain performance near the theoretical limits.

2. Lens-based Image Reconstruction

Data is gathered from a coherent lens-based imaging system, as depicted in Figure 1. Since the system is coherent, the magnitude and phase of the complex wavefront that strikes the lens are measured by the imaging system. If the lens is properly designed, and the array is placed at the correct focal zone, then the image of the target object will be obtained simply by taking the magnitude of the measured signal, $s(x,y) = \sqrt{I^2 + Q^2}$. This image will appear inverted due to the image-reversing characteristic of the lens. If the lens can be assumed to be 'thin,' then the location of the array will obey the Gaussian Lens Formula for optimal focus

$$\frac{1}{s_o} + \frac{1}{s_i} = \frac{1}{f} \tag{3}$$

where f is the focal length of the lens.

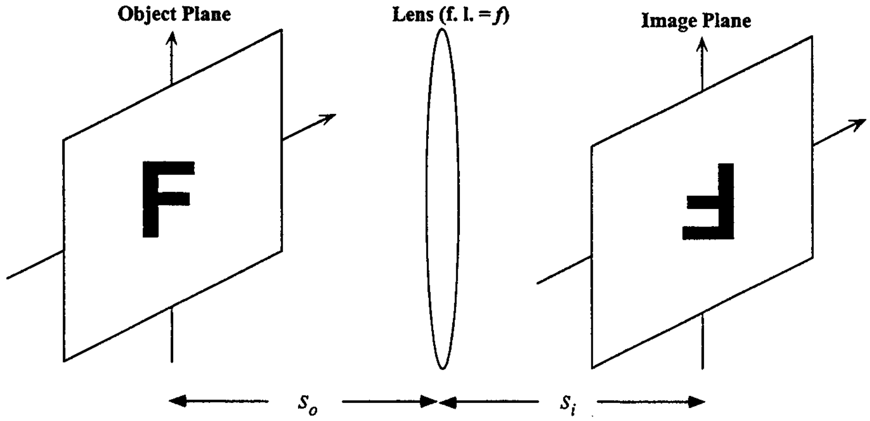


Figure 1 Lens-based imaging system.

2.1 Thin-lens requirement

All of the analysis done in this section relies on the thin-lens approximation. The critical element of the thin lens requirement is that a ray entering the lens at coordinates (x, y) can be approximated as leaving the lens at the same (x, y) coordinates. This allows wave propagation through the lens to be approximated as a simple phase-shift of the wave.

2.2 Lens-based imaging simulation

To simulate a lens-based imaging system, the scattered wavefront from a test target composed of 12 points arranged to form the letter F was computed by superposing the complex phase of each of the point scatterers over an (x, y) aperture. This complex phase is simply $e^{-jk\sqrt{(x-x_s)^2+(y-y_s)^2+z_s^2}}$ where $k = 2\pi/\lambda$, $(x, y, 0)$ are the aperture coordinates, and (x_s, y_s, z_s) are the source point coordinates. This aperture was chosen to be just on the object side of the lens plane. The real-part of this scattered wavefront is shown in Figure 2. The imaging system was configured for $s_o = s_i = 2f$.

The wavefront (of Figure 2) was passed through the lens by multiplying by $e^{-j\phi(x,y)}$ where $\phi(x, y)$ is the phase-shift through the lens. This phase function was chosen so that a plane-wave normally incident on the lens aperture would focus at the focal length, *f*. The real-part of the phase-front after passing through the lens is shown in Figure 3.

After passing through the lens, the phase-front will converge as it propagates toward the array. This propagation can be determined using Fourier optics techniques[1]. The phase-front can be 2-D Fourier Transformed which decomposes the phase-front into discrete plane wave components. These plane wave components can then simply be phase-shifted to determine their amplitude and phase at any other depth, z. The actual wavefront at this depth is then determined by inverse 2-D Fourier Transform of the plane-wave components. The magnitude of the wavefront at the focal-plane is shown in Figure 4. The image is inverted (as expected) and is reasonably well focused with each discrete point in the F clearly resolved. There is, however, some undesirable spreading of each point's response. This is perhaps due to the non-paraxial nature of the example simulated.

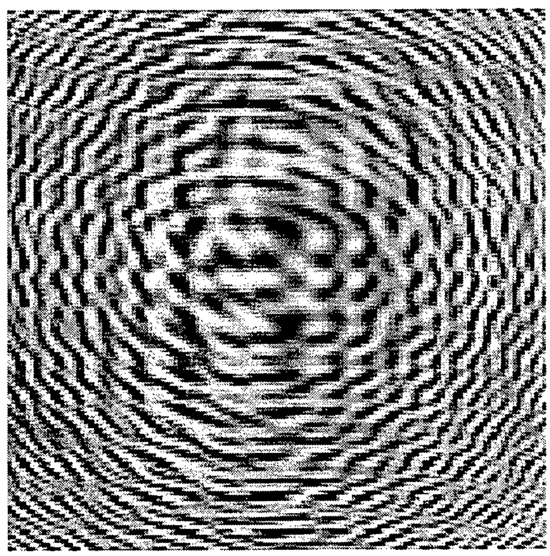


Figure 2 Object phase-front just before impinging on the lens.

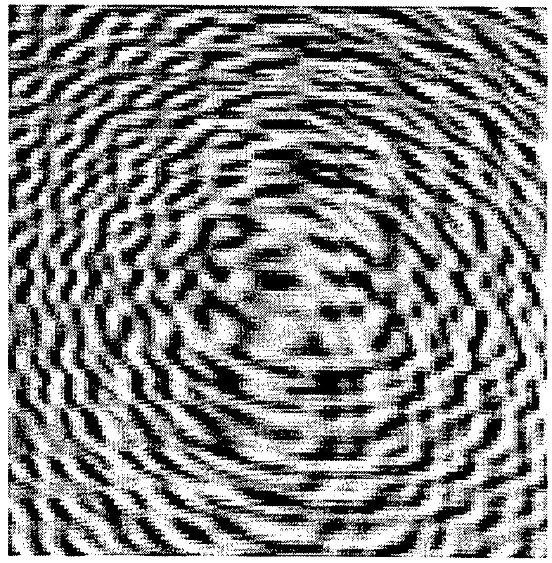


Figure 3 Object phase-front just after passing through the lens.

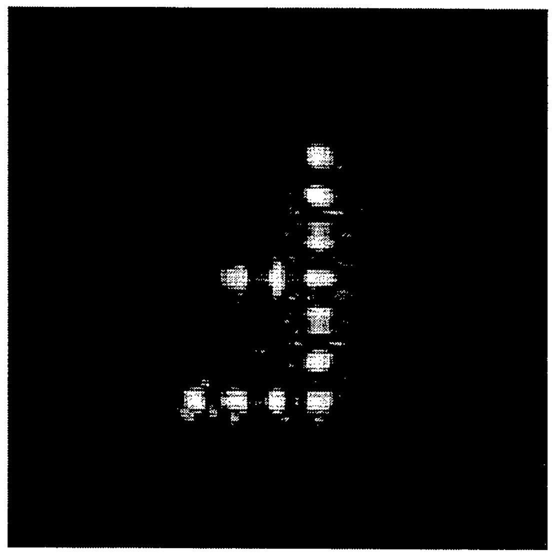


Figure 4 Image magnitude at the focal plane.

2.3 Correction of non-ideal array placement

Fourier optics techniques can be used to correct for placement of the array at positions other than the ideal focal plane. Figure 5 shows an image that would be obtained if the array were placed at 75% of the correct distance from the lens. The coherent data obtained by the array, can however, be 'forward-propagated' using plane-wave decomposition to the correct focal plane of the array. This results in the

image shown in Figure 6, which is essentially identical to the image obtained in Figure 4.

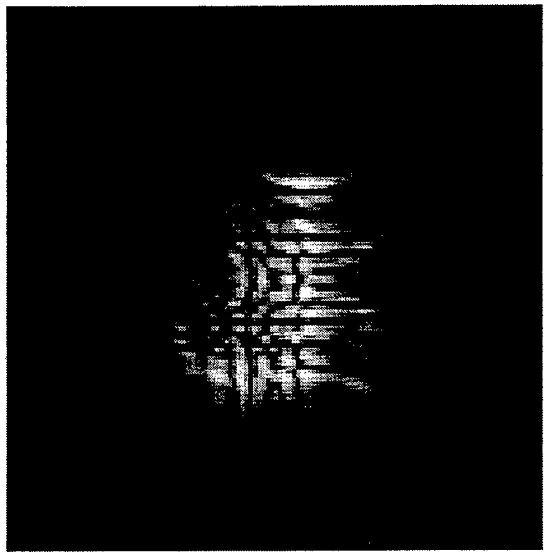


Figure 5 Image magnitude at 75% of the focal distance.

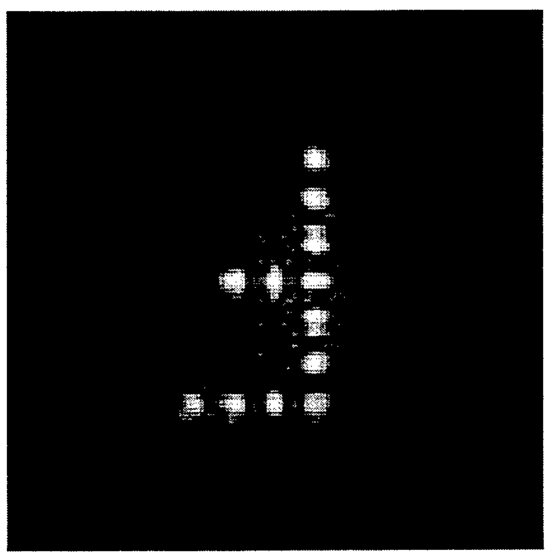


Figure 6 Image magnitude after correction to the correct focal distance using 'forward-propagation.'

2.4 Back-propagation to the object plane

A superior image formation method to that discussed in Section 2.3 is available. Instead of simply forward or back propagating the wavefront to the focal plane, the wavefront can be back-propagated to the lens plane, phase-shifted through the lens,

and back-propagated to the object plane. This forms a virtual image of the object. Most importantly, this technique removes the effect of the lens. Therefore, as long as the shape of the lens is known, any aberration that it causes in the image can be removed by this process. The reconstructed image of the F test object obtained in this manner is shown in Figure 7. This image is tightly focused and does not have the sidelobe artifacts of the lens-only reconstruction shown in Figures 4 and 6. Note that in Figure 7 the image-reversal is not present.

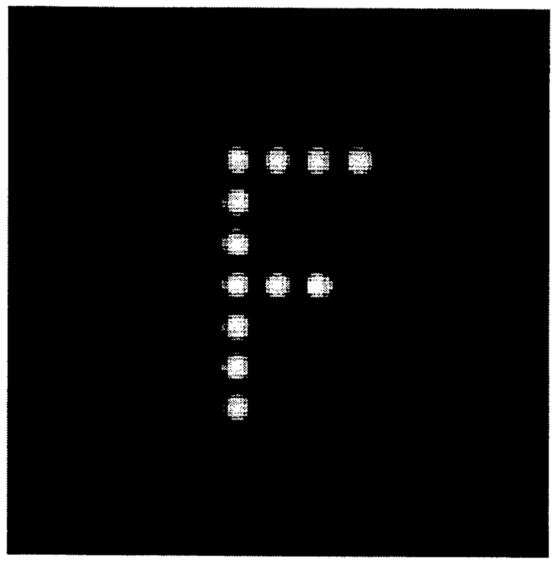


Figure 7 Image magnitude after 'back-propagation' with phase-correction for the lens.

3. Application to full 3-D imaging

The example demonstrated in Figures 2-7 was simulated using a single frequency. These techniques are, however, fully adaptable to wideband 3-D imaging. The effect of the lens on each frequency component of a wideband system can be eliminated using the technique demonstrated in Section 2.4. After the effect of the lens is removed, the efficient 3-D holographic reconstruction techniques (developed at PNNL) can be applied. Three-dimensional imaging is important in the lens-based imaging system, since it will allow a virtually unlimited depth-of-field (or depth-of-focus).

The following results demonstrate the effectiveness of these techniques for wideband, three-dimensional imaging. For ease of simulation, the wideband 3-D reconstruction

algorithm was reduced to a two-dimensional case with a single cross-range dimension and one time/range dimension.

The goals of the following simulation are first to simulate the time-domain data received by an array placed near the focal plane of a lens, and second to demonstrate how that time domain data can be reconstructed.

It is most convenient to simulate the data first in the frequency domain. The complex wavefront emanating from point scatterers is determined using the same method as Section 2.2. An example phase-distribution from a single point scatterer is shown in Figure 8, where the horizontal axis is cross-range and the vertical axis is frequency. The data undergoes a frequency-dependent phase shift when passing through the lens, as shown for a single point scatterer in Figure 9. After forward propagation to the focal plane, each frequency component is focused laterally by the lens, as shown in Figure 10. This frequency-domain data is converted back to the time-domain by inverse Fourier Transform. The amplitude of the time-domain waveforms that would be received by the array are shown in Figure 11. Because the point scatterer was placed at the focal plane and on the axis of the lens, the point scatterer is imaged with good resolution and little or no distortion.

Wideband reconstruction of the data shown in Figure 11, is accomplished in the following manner. The time-domain waveform at each transducer position is Fourier Transformed to form frequency-domain data. The complex wavefront of each frequency component is back-propagated to the lens and phase-shifted through the lens. At this point, the effect of the lens has been removed, and the 3-D (reduced to 2-D in this case) FFT based holographic reconstruction algorithm can be applied. The reconstructed image of the single point scatterer is shown in Figure 12.

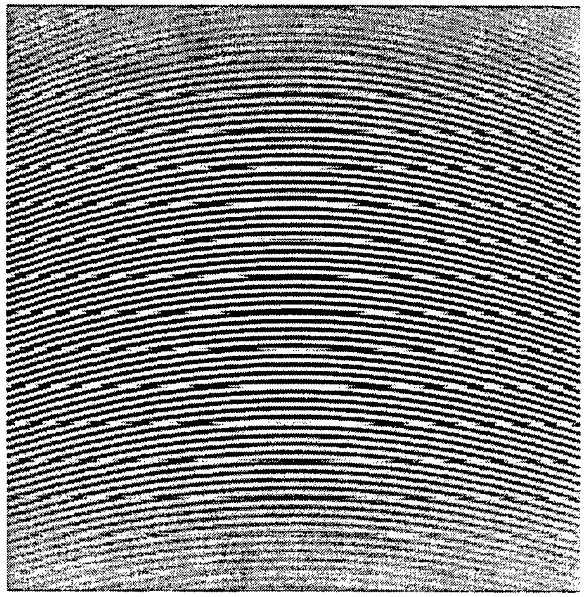


Figure 8 Object wavefront phase distribution from a single point scatterer just prior to impinging on the lens. The horizontal axis is the cross-range dimension and the vertical axis is frequency.

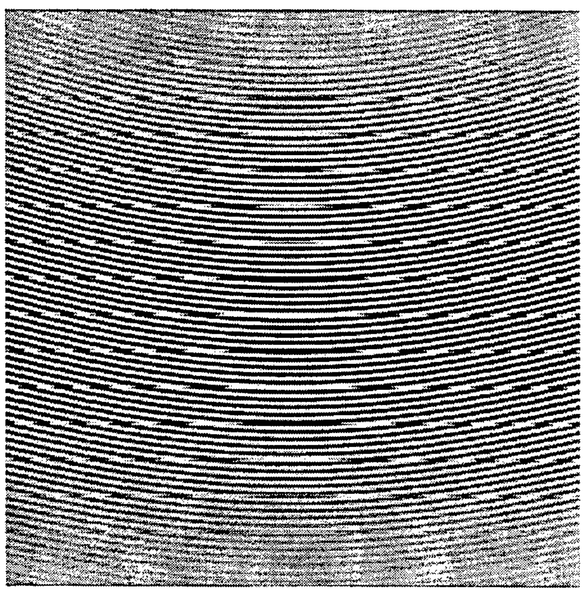


Figure 9 Object wavefront phase distribution from a single point scatterer just after passing through the lens. The horizontal axis is the cross-range dimension and the vertical axis is frequency.

Comparison of the images in Figures 11 and 12 shows minimal difference in the resolution of the image of the point scatterer. For point scatterers that are placed away from the focal plane of the lens and away from the axis of the lens, the wideband image reconstruction algorithm is superior to simply allowing the lens to focus the data. This is shown clearly in Figure 13. In this figure, seven point scatterers were placed at the same horizontal position and at seven different depths. The depths selected were 1.3 , 1.4, 1.5, 1.6, 1.7, 1.8, and 1.9 times the width of the aperture. The focal plane of the lens is at a depth of 1.6 times the width of the aperture (F-1.6). The images on the left in Figure 13 represent the simplest image reconstruction technique of allowing the lens to perform all spatial focusing. The images on the right in Figure 13 are reconstructed images obtained using the full wideband 3-D (reduced to 2-D in this case) reconstruction algorithm described above. The seven point scatterers were centered on the axis of the lens in the top pair of images. The remaining pairs of images were offset from center by 0.1, 0.2, and 0.3 times the aperture width. This data clearly shows the limited depth of field present in the lens-only based images. The middle depths near the focal plane are tightly focused, and the points away from the focal plane are significantly out of focus. The lateral shifting away from the axis of the lens also produces a distortion. The points no longer appear to be at the correct lateral or depth positions. The data reconstructed using PNNL's wideband image reconstruction techniques shows neither of these limitations. There is no apparent distortion of the positions of the point scatterers, and each point is imaged with the diffraction-limited resolution. In fact, the point scatterer nearest to the lens show the highest resolution since the F-number is the lowest at these points. This is despite the fact that they are not near the focal plane of the array.

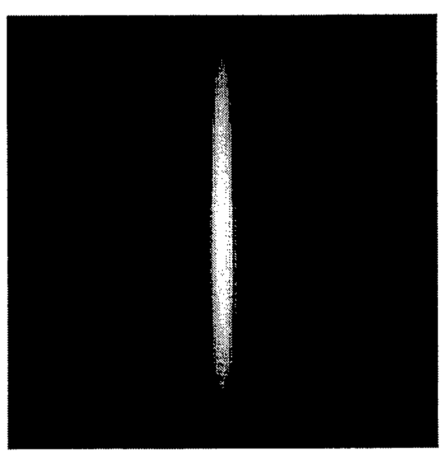


Figure 10 Object wavefront amplitude distribution from a single point scatterer after propagating to the focal plane. The horizontal axis is the cross-range dimension and the vertical axis is frequency.

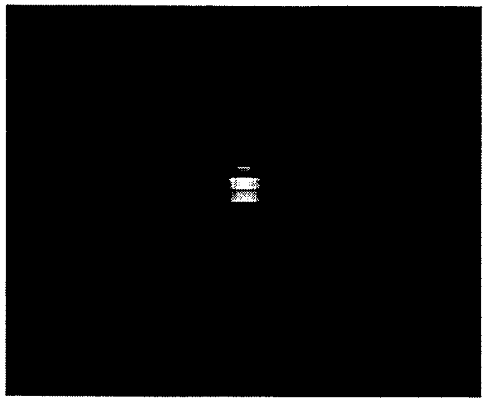


Figure 11 Simulated time-domain waveforms from a single point scatterer received by the array. The horizontal axis is the cross-range dimension and the vertical axis is time/range.

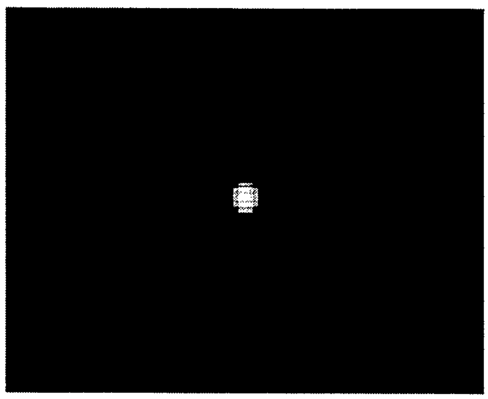


Figure 12 Image reconstructed from a single point scatterer using PNNL's wideband algorithm. The horizontal axis is the cross-range dimension and the vertical axis is depth/range.

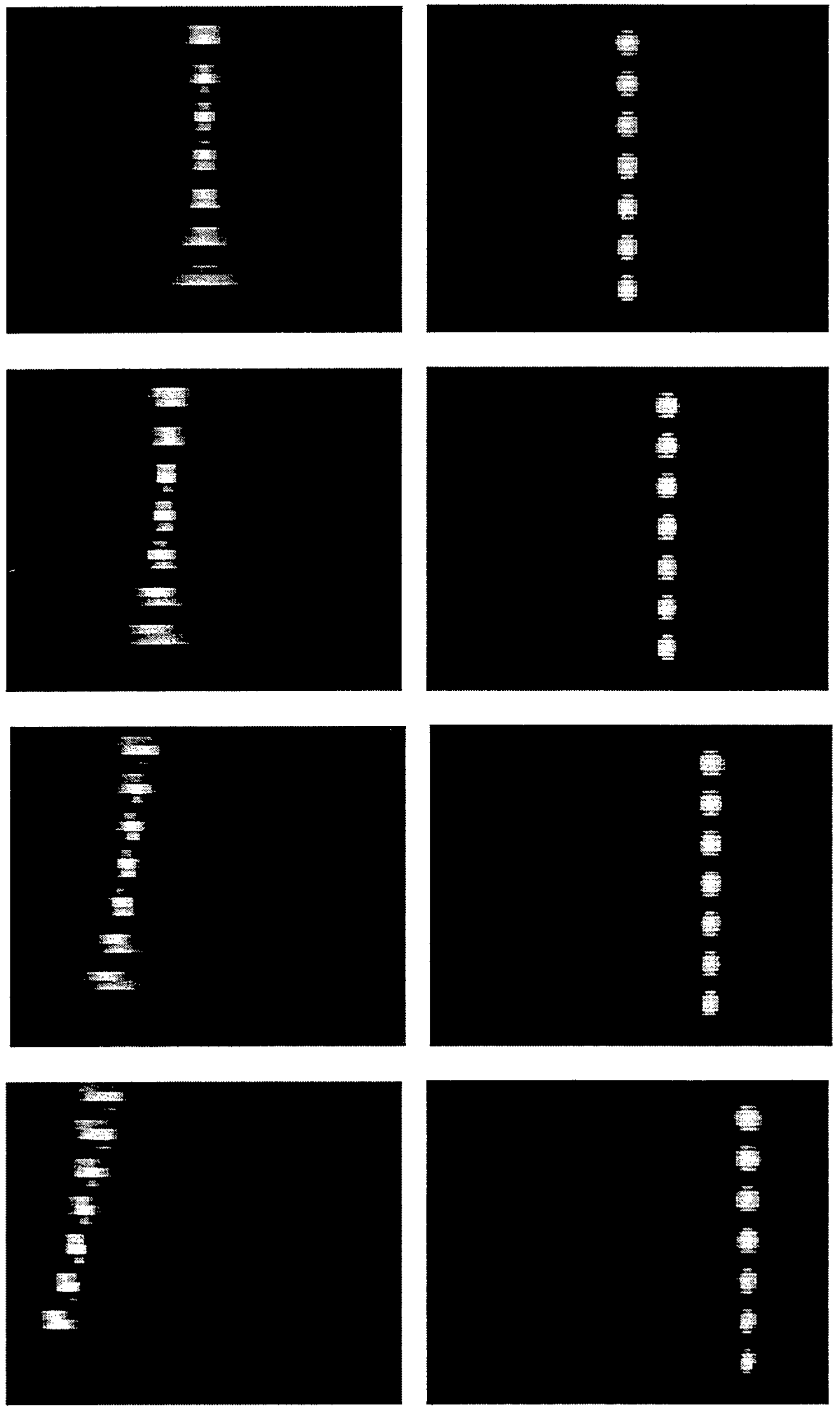


Figure 13 Comparison of time-domain waveform images (left) and full wideband reconstructed images (right) for seven point scatters at depths ranging from 1.3 to 1.9 times the aperture width at various positions across the aperture.

4. Conclusions

Holographic, or Fourier optic, reconstruction techniques can be applied to lens-based imaging systems. The only significant limitation in the analysis is that the thin-lens approximation must be valid. These techniques have been demonstrated on simulated single-frequency and wideband data. The extension to full three-dimensional imaging is straightforward. Three-dimensional imaging using reconstruction techniques developed at PNNL allows fully-focused three-dimensional imaging with an unlimited depth of field using a 2-D array, with or without a lens. If a lens is used, known aberrations that it causes may be removed from the images algorithmically.

5. References

[1] Goodman, J. W., **Introduction to Fourier Optics**, McGraw-Hill, 1968.

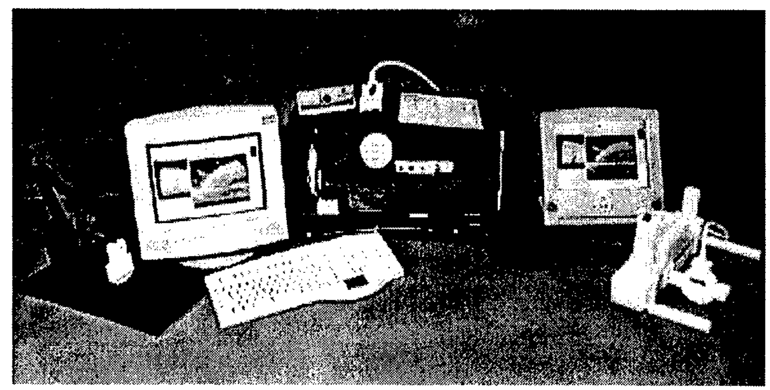
APPENDIX F

Appendix F: ***MUSTPAC-1: 3-D Ultrasound Telemedicine System, Web page circa October 1996.***

MUSTPAC-1: 3-D Ultrasound Telemedicine System

Medical UltraSound, Three-dimensional and Portable with Advanced Communication

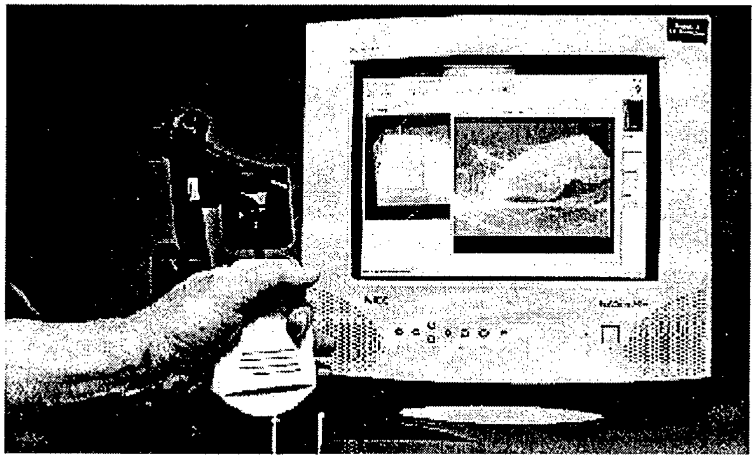
The MUSTPAC-1 is a fully functional 3-D ultrasound medical imaging system that incorporates the following elements (**right-to-left** in picture):



- Backpackable field unit containing
  - "3-D Paddle" electromechanical scanner (at extreme right)
  - Silicon Graphics Presenter(TM) flat panel display (to right of backpack)
  - Hitachi EUB-905 ultrasound machine (in backpack, top section, with cord)
  - Silicon Graphics Indy(TM) computer (in backpack bottom section)
  - Teleconferencing camera (on backpack, top left)
  - Keyboard with integral touchpad (in front of backpack)
- High-resolution color monitor.
- Virtual ultrasound probe (Immersion Probe) to provide expert ultrasound diagnosticians with a familiar interface that is easy to learn and easy to use.

The MUSTPAC is unique in that it provides an ultrasound telemedicine capability that is effective, requires very little training for anyone, does not require a highly skilled operator at the patient's side, and operates well even in a low-bandwidth store-and-forward file transfer mode. This is accomplished by 1) scanning a fairly large volume of the patient at one time so that diagnosis during the

scan is not required, and 2) providing the remote diagnostician with a familiar interface -- a "virtual ultrasound probe" --that mimics conventional 2-D ultrasound, so that their years of experience and hand-eye coordination can be brought to bear using the MUSTPAC after only a few minutes practice.



The "virtual ultrasound probe" interface is implemented using a modified Immersion Probe(TM) or equivalent 6-D sensing arm (3-D position, 2-D tilt, plus rotation).Position and orientation of the probe is used by the MUSTPAC's visualization software (TeleInViVo(TM), from Fraunhofer CRCG) to "reslice" the 3-D ultrasound data along arbitrary cutting planes. The screen view is updated in real time (5-10 updates per second) so the diagnosticians can work with MUSTPAC 3-D scans in the same way that they would with a real patient and a conventional 2-D ultrasound system.

The MUSTPAC-1 prototype is an interim deliverable in a continuing research program funded by DARPA. At present, only one unit has been fully fabricated. However, the system components are all either off-the-shelf or easy to fabricate, so it would be straightforward to produce additional units of the same design.

At present, the MUSTPAC system has only limited approval by the FDA, so that clinical investigations using it require IRB-approved medical protocols with informed consent etc. In experience to date, these approvals have been easy to obtain because the MUSTPAC introduces no significant safety issues -- its sensor technology is just an unmodified conventional 2D ultrasound system, combined with a battery-powered, electrically isolated, mechanical scanner.

Planned future developments include engineering improvements, 510(k)or similar FDA approval for routine use by the military, and clinical studies regarding specific applications.

The MUSTPAC-1 prototype weighs approximately 85 pounds in its backpack configuration. This weight includes an ultrasound system(Hitachi EUB-905), 3D paddle, Indy computer with camera and large LCD screen -- everything needed to acquire3D ultrasound data, visualize it locally, transmit the data to a remote site, and consult via teleconference. The pack requires AC power and a network connection that supports the TCP/IP protocol. Battery operation has also been demonstrated using a commercial UPS unit (45 minutes, 50 pounds). Satellite operation has been demonstrated using sync routers that transparently extend network operation across a satellite link. Planned system upgrades will result in significantly lower weight, increased battery operation times, and additional communication options.

Development of the MUSTPAC-1 was performed using "rapid prototyping" procedures and based on experience with the predecessor system developed in FY95. Although MUSTPAC-1 had been planned for several months earlier, the final decision to allocate funding and develop a prototype did not occur until April 1996. Acquisition, fabrication, and software development was performed on a very rapid schedule, and the completed backpack was shipped to MATMO at Ft.Detrick on 3 July 96. From there it underwent a series of pre-deployment evaluations under the supervision of the Center for Total Access (CTA, Fort Gordon Georgia). After the performance evaluation was completed, the system was shipped to Landstuhl, Germany, arriving on Friday, 26 July 96. It was unpacked, operational, and running demonstrations within 2 hours of arrival at Landstuhl. Briefings were provided to the Landstuhl commander, COL Kiley, on 30 July 96and to COL Farmer on 31 July 1996. It was delivered to the European Command (EUCOM) on 4 August 96.

On 7 August 1996, Dr. Macedonia deployed the MUSTPAC to the 212th Mobile Army Surgical Hospital, Camp Bedrock, Tuzla, Bosnia. The machine was operational upon arrival and communications links were established using standard ethernet protocols. Data was transmitted back through a microwave link to Eagle Base Tuzla(12 km away) and then fed through a Ku Band Satellite link to MUSTPAC2 in Landstuhl, Germany. Other receiving sites included Richland WA, Tacoma WA, Providence RI, and Washington D.C. The machine also operated in a stand-alone mode. The unit was redeployed to Washington DC on 8 September 1996.

APPENDIX G

Appendix G: ***MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater, Final Report, "Bosnia Task", PNL IRB #94-6-1, Project #22258***

MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater

Final Report, "Bosnia Task", PNL IRB #94-6-1, Project #22258

Report Date: April 14, 1997

Richard J. (Rik) Littlefield
Battelle Pacific Northwest Laboratories
Richland, WA 99352

MAJ Christian R. Macedonia, MD
U.S. Army Medical Corp

ABSTRACT

Ultrasound is a popular technology for medical imaging of soft tissues because it is inexpensive, safe, and relatively portable. However, the use of ultrasound imaging in remote areas has been limited because conventional real-time 2-D (two-dimensional) ultrasound imaging requires that a highly skilled operator, capable of diagnostic decisions, be present at the patient's location to point the data acquisition probe. 3-D ultrasound data acquisition has the potential to remove this limitation, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This capability is illustrated by the MUSTPAC-1, a portable 3-D ultrasound telemedicine system recently developed for the U.S. military. In August 1996, the MUSTPAC-1 system was field-tested by the U.S. Army in Germany and Bosnia. This report discusses design and implementation of the MUSTPAC-1 system and summarizes results of the Bosnia field test.

INTRODUCTION

Ultrasound is a commonly used method for medical imaging of soft tissues. It is safe, inexpensive, and quick.

However, conventional 2-D (two-dimensional) ultrasound imaging has the significant drawback of requiring a highly skilled operator to be physically present at the patient's location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to place the image acquisition probe at the correct location and orientation to see what needs to be seen.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe so as to locate the gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient's internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing makes it problematic to use conventional 2-D ultrasound in a telemedicine setting where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound allows high quality scans to be taken by an operator with limited training and no diagnostic skills. This is accomplished by having the system scan a fairly large volume of the subject's anatomy at one time, without interpretation, so that the operator can use a simple "point-and-shoot" strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that surrounds the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done by an ultrasound expert located somewhere else.

In the summer of 1996, a prototype 3-D ultrasound telemedicine system was developed for use by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was tested using a variety of data communication links between Germany, Bosnia, and several sites in the U.S. The system worked well, experiencing no major failures and exceeding expectations in some areas.

This report discusses design and implementation of the MUSTPAC-1 system and summarizes results of the Bosnia field test.

THE MUSTPAC-1 SYSTEM

OVERVIEW. The name MUSTPAC-1 is an acronym for Medical UltraSound, Three dimensional and Portable, with Advanced Communications - 1st generation. MUSTPAC-1 is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation.

The MUSTPAC-1 system is optimized for use in a telemedicine framework. It provides the unique capability that high quality ultrasound scans can be taken by an operator with no diagnostic skills, little training, and no online connection to an expert.

Typically MUSTPAC-1 is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across their skin over the area of interest (Figure 1). During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric dataset of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.

Figure 1. Acquiring a 3-D abdominal scan using the 3-D Paddle and actual ultrasound probe.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician.

Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D dataset simply by moving the probe as if they were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.

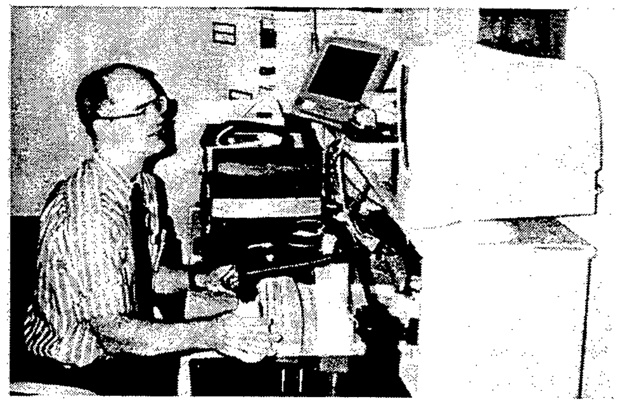


Figure 2. Interpreting a 3-D scan using the Virtual Ultrasound Probe at a diagnostic workstation.

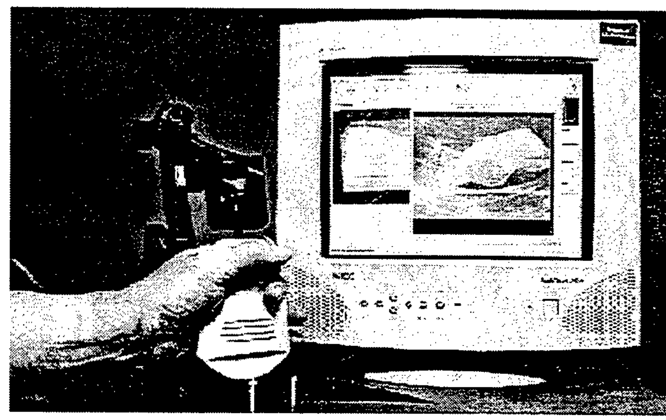


Figure 3. Closeup of the Virtual Ultrasound Probe and diagnostic workstation display.

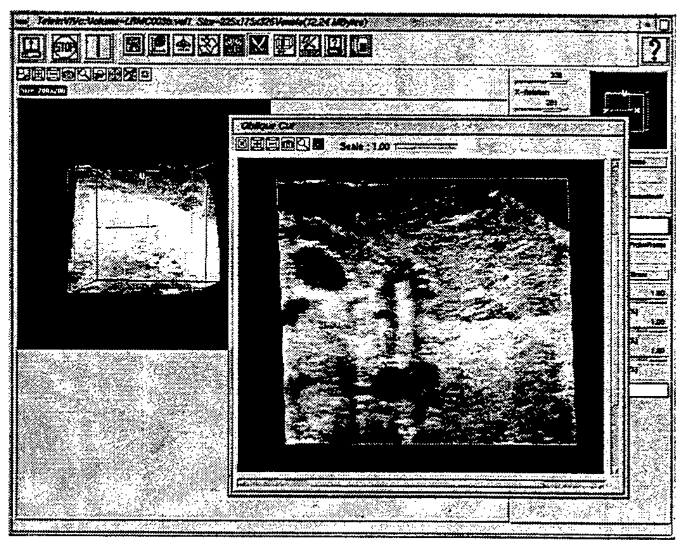


Figure 4. Actual diagnostic display (human liver with clotting in major veins).

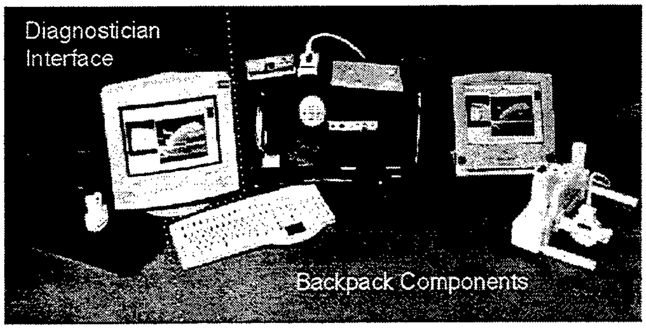


Figure 5. MUSTPAC-1 system components as packaged for military field evaluation.

SYSTEM COMPONENTS AND PACKAGING. Major components of the MUSTPAC-1 system are shown in Figure 5. These components include (right-to-left):

- Backpackable field unit containing "3-D Paddle" electromechanical scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display (to right of backpack)
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)
- Keyboard with integral touchpad (in front of backpack)
- High-resolution color monitor.
- Virtual ultrasound probe
- TeleInViVo™ visualization software (a product of Fraunhofer CRCG, Providence RI, customized for MUSTPAC-1).
- Other custom software for data acquisition and control.

MUSTPAC-1 Principles of Operation

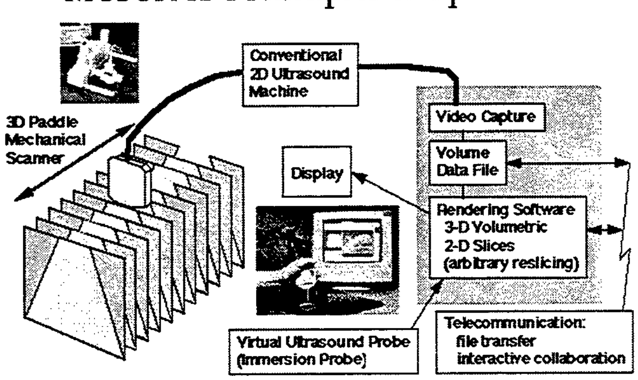


Figure 6. Major components, operations, and data flows in MUSTPAC-1.

PRINCIPLES OF OPERATION. Figure 6 diagrams the major components, operations, and data flows within the MUSTPAC-1 system.

Scanning. Volumetric scanning is done by mechanically moving the probe of a conventional off-the-shelf ultrasound machine (Hitachi EUB-905). As the probe moves, the ultrasound machine generates a sequence of video images showing a 2-D slice of the subject under the probe. A computer digitizes the sequence of 2-D images and assembles them to form a 3-D volumetric dataset.

Moving the ultrasound probe is accomplished by using an electromechanical device attached to it. In the MUSTPAC-1, this device is called the "3-D Paddle". It is a battery-powered device that moves the probe under motor control, in a straight line, at a precise speed of 1.0 cm/second. This linear scanning movement generates a set of parallel images that naturally assemble to form a dense rectangular 3D dataset.

Scans are usually taken at 15 fps (frames per second), using a 3.5 MHz or 5 MHz convex-face sector-scan probe. With typical penetration depths, this results in scanning a region 6 cm wide at the skin surface and 20 cm wide at 15 cm deep, with a voxel (volume element) size of 0.7 mm on each axis.

It is important to note that the 3-D datasets captured by this process represent a sort of "snapshot" of the subject's anatomy. Anatomical movement is not captured, except in the form of motion artifacts that the diagnostician must learn to ignore.

In addition to the 3-D ultrasound dataset generated during the scan, the MUSTPAC-1 also captures a single-frame image from each of two attached video cameras. Typically these are used to record placement of the 3-D Paddle on the subject's body.

Visualization for Analysis and Diagnosis. The MUSTPAC-1 can generate several kinds of images:

* 2-D slices at arbitrary positions and orientations.
* 3-D volumes using "maximum intensity projection" (MIP) and similar techniques for combining the values of dataset volume elements (voxels).
* 3-D surfaces defined by threshold values and rendered using one of several shading techniques.

Several images can be shown simultaneously. The most common practice is to combine a large 2-D slice image with a small 3-D volumetric image (Figure 4). The 2-D slice shows detail that is useful diagnostically,

while the 3-D volumetric image provides context by showing location of the 2-D slice within the volume.

Virtual Ultrasound Probe. To provide diagnosticians with a familiar, convenient user interface, the MUSTPAC-1 is equipped with a Virtual Ultrasound Probe (Figure 3). This is a hand-held 6-D input device that controls 2-D slicing of volumetric datasets in the same way that a real ultrasound probe controls 2-D imaging of patients. That is, theVirtual Ultrasound Probe looks, feels, and acts like a real ultrasound probe in that the on-screen image is constantly updated in real time (typically 5-10 times per second) to reflect the position and orientation of the probe. (Again, this real time updating does not reflect anatomical movement, which is not captured in the datasets).

In the MUSTPAC-1, the Virtual Ultrasound Probe is implemented using an Immersion Probe™ (product of Immersion Corporation) with a dummy ultrasound probe added to it. Other 6-D input devices, such as magnetic free-space trackers, could easily be substituted for the Immersion Probe™.

Data Communication. The MUSTPAC-1 system provides two major methods of data communication: batch mode file transmission and TeleInViVo™ incremental transmission.

In batch mode file transmission, 3-D datasets and associated files are transferred using the Internet standard "ftp" protocol. These transfers are for ease of use over relatively high bandwidth communication channels. They are initiated by the user from a "desktop" graphical interface using a drag-and-drop procedure.

Incremental communication capabilities are also built into the TeleInViVo visualization program. These capabilities allow all or part of the full dataset to be transferred quickly at reduced resolution, while the user interactively evaluates the images. Typical use is envisioned to be transfer of the entire dataset with resolution reduced by 4X per axis (64X overall), followed by transmission of an identified region of interest at the full resolution of the dataset.

Image Quality. The MUSTPAC-1 produces diagnostic quality images.

At maximum resolution, the saved 3-D datasets capture all detail present in the video output signal from the Hitachi EUB-905 (640x480 pixels at 8-bit gray scale). However, maximum resolution capture often is not justified due to noise and fuzziness in the ultrasound imaging process.

Better results are usually obtained by a simple process that filters the digitized images and samples the filter output to construct the saved 3D dataset. Operator controls are provided to select the amount of filtering. Typical settings produce one dataset voxel as the average of a 2x2 block of pixels from the digitized video image.

There is no image degradation due to storage and transmission of the 3D datasets. All transmission protocols incorporate error detection and correction/retransmission. Only non-lossy (exact) compression techniques are used in the MUSTPAC-1.

FIELD EXPERIENCES. In August, 1996, the MUSTPAC-1 system was deployed by the U.S. Army to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia. A second MUSTPAC-1 placed at the Army's Landstuhl Regional Medical Center in Germany served as the primary receiving station.

Scanning. During the deployment, a total of 72 scans were performed on 42 volunteers, as follows:

Scan Type	Number
Right Upper Quadrant	55
Pelvis/Uterus/Posterior Cul-de-Sac	7
Placenta	5
Renal	3
Extremity	1
Aorta	1
Total	**72**

Most of these scans were taken by operators with no ultrasound diagnostic skills and minimal MUSTPAC-1 training (typically 10 minutes). No formal evaluation of the image quality has yet been performed. Informal evaluation by a variety of experienced ultrasound users suggests that the quality of the scans was largely independent of an operator's level of training and generally ranged from adequate to very good.

Communications. Most transfers between Bosnia and Germany were performed using ftp over a T1/E1 (roughly 1 megabit/second) geosynchronous satellite link leased by the Army. Despite a round-trip packet delay of 580-600 ms, net transfer rates of roughly 50 Kbytes/second were routinely achieved. Thus typical 3-D datasets of 6-12 Mbytes required only a few minutes to transfer even without compression.

As exercises, 3-D datasets were also transferred over two slower communication links. One of these links was between Germany and Washington DC (USA) at 56 Kbits/sec using the International Maritime Satellite System (INMARSAT) and its associated telephone system ISDN link. The other was between Bosnia and Germany using the Army's Tactical Packet Network (TACNET) at 9.6 Kbits/sec. These transfers were also successful, but would be too slow for

most routine applications without the use of more aggressive data compression techniques.

Diagnostic Usability. During the Bosnia deployment and in the 6 months since its completion, the MUSTPAC-1 system has been operated by approximately 20 experienced ultrasound users. Informal evaluation suggests that the system is very easily learned. One striking observation is that no experienced ultrasound user to date has required more than 5 minutes practice with the Virtual Ultrasound Probe to begin making medical interpretations of 3-D scans that they had not previously seen. However, no formal studies of usability or effectiveness have been performed, and such studies will be needed to determine the degree of diagnostic accuracy provided by the MUSTPAC's techniques.

Adverse Events. During the field test in Bosnia, one subject was physically pinched by the 3-D Paddle, resulting in a small superficial bruise requiring no medical treatment. The operational procedure for the 3-D Paddle was immediately revised to avoid a repetition, and the 3-D Paddle has been redesigned to make pinching less likely in future designs.

LIMITATIONS. While MUSTPAC-1 provides a unique capability for ultrasound telemedicine, it is a first-generation system with significant limitations. These limitations include:

- No Doppler. Neither the Hitachi EUB-905 ultrasound scanner nor any of the MUSTPAC-1 software supports any Doppler capability at this time. This means that MUSTPAC-1 provides no direct visualization of blood flow.

- Inflexible scanning. The motor-driven 3-D Paddle is simple to use and robust, but provides only linear translation parallel scanning. Freehand scanning would be more flexible and simpler to use in many parts of the body.

- No anatomic motion. Conventional real-time 2-D ultrasound shows anatomic motion, such as pulsing arteries, as a moving image on screen. This is diagnostically useful. However, the 3-D scans captured by MUSTPAC-1 are static snapshots. Generally speaking, with MUSTPAC-1 anatomic motion produces image artifacts that the diagnostician must ignore.

Ongoing development of the MUSTPAC system is planned to relieve these limitations.

SUMMARY

3-D ultrasound data acquisition can potentially enable effective use of ultrasound imaging in a telemedicine setting, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This capability is illustrated by the MUSTPAC-1, a portable 3-D ultrasound telemedicine system recently developed for the U.S. military and successfully field-tested by the U.S.Army in Germany and Bosnia in August 1996.

ACKNOWLEDGMENTS

Development and testing of the MUSTPAC-1 was funded by the Defense Advanced Research Projects Agency (DARPA) under contract number DAMD-17-94-C-4127. We are grateful to our program managers Dr. Rick Satava and Dr. Wally Smith for their support and guidance.

The opinions expressed in this article are those of the primary authors and do not necessarily reflect official policy of the United States Department of Defense or Department of Energy.

ADDITIONAL SOURCES

"MUSTPAC-1: 3-D Ultrasound Telemedicine System", `http://www.pnl.gov/3dmed`, Dec.1996.

"Backpack remote medicine proves its worth", Jane's International Defense Review, Feb.1997, pg.15.

IEEE Engineering in Medicine and Biology Magazine, Theme Section titled "Advances in Ultrasound", V.15, No.6, Nov/Dec 1996, pp.18-101.

APPENDIX H

Appendix H: *"Ultrasound marches to the front"*, Portable Design Magazine cover article, June 1997.

Ultrasound marches to the front

John H. Mayer, Contributing Editor

In military medical care, it's axiomatic that what happens during the golden hour—the 60 minutes immediately following a serious wound or injury—is key to patient survival. Unfortunately, sophisticated diagnostic equipment, crucial to treat life threatening wounds swiftly, has been too cumbersome to take into the field, and the golden hour often passes—along with the casualty. What's needed is better portable medical gear.

Now, a joint effort by researchers at Pacific Northwest National Laboratory (Richland, Wash.) changes the portable picture. Working with medical technology experts at the Defense Advanced Research Projects Agency (DARPA) and designers at the U.S. Army Medical Research and Materiel Command, a design team has developed just such a system—a portable ultrasound imager. It's purpose is to bring the benefits of sophisticated ultrasound imaging—conventionally used in hospitals—to the front lines in combat situations.

A multidisciplinary design team uses off-the-shelf subsystems to rapidly develop a portable telemedicine box.

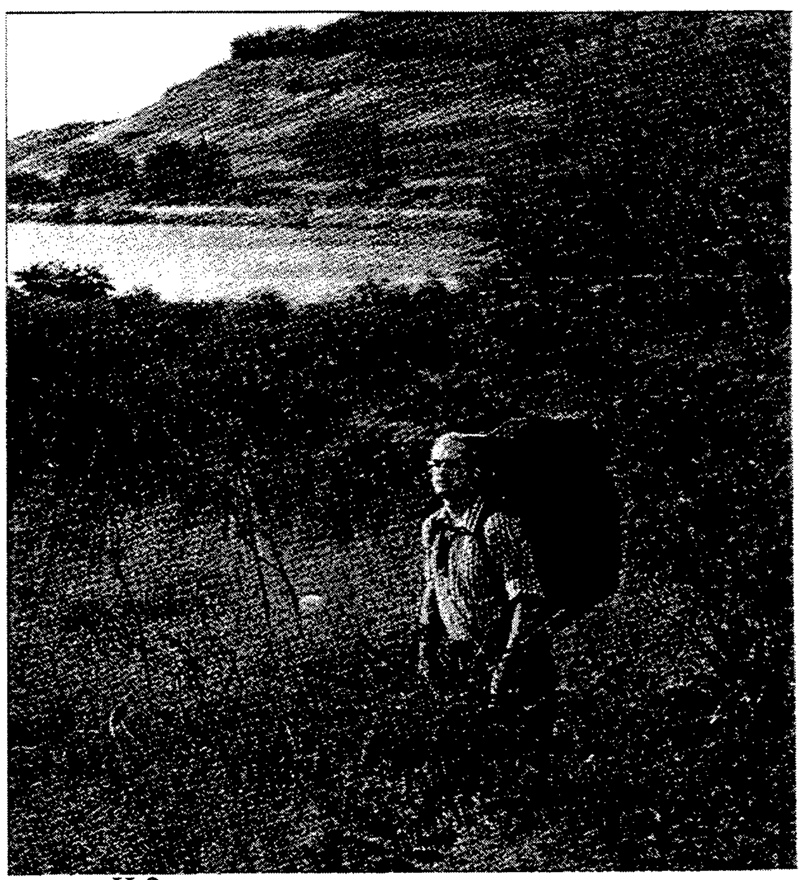
Commercial potential

Promising to someday reduce the number of battlefield deaths, while offering tremendous commercial potential, the joint design effort resulted in the design of what's called a Medical Ultrasound, Three-dimensional and Portable with Advanced Communications box (any GI will tell you it's easier to call it by its acronym: MUSTPAC-1).

"If a patient's bleeding in the field or, for that matter, in some remote county in West Virginia, I don't have time to take him to an MRI," says Dr. Christian Macedonia, principal medical investigator on the project. "The direction medical diagnostics has to go is toward making systems that are lightweight and portable in design so you can take them to the patient." Macedonia is also a major with the U.S. Army Medical Corps at Georgetown University Medical Center, so he knows of what he speaks.

Ease of use is key

The MUSTPAC-1 permits a semiskilled operator to perform 3-D scans of an injured soldier and send those images for interpretation to experts anywhere in the world. Macedonia is credited with much of the initial vision for MUSTPAC. In fact, he began exploring the use of 3-D ultrasound while he was a medical student in the early 1990s.



At that time, Macedonia was interested in exploring how different chest ventilation methods affected blood flow throughout the body. While he uncovered significant research on Doppler ultrasound, one of his criticisms was that it couldn't be used to track moving objects. "It occurred to me that we have radar systems that can track missiles in flight, so why can't we apply some defense technology toward this problem?"

It took a few years, but Macedonia eventually hacked together a prototype that embodied his ideas. Using off-the-shelf components, he pieced together a Macintosh 7100 computer, a trackball keyboard, and an ultrasound machine. He used a scan converter to transform the Macintosh video output to NTSC video and then ran it back out the monitor of the ultrasound machine. Did it work? "Yes," tells Macedonia, "but it generated images that were nice to look at, but weren't particularly useful."

Knowing he'd reached his technical limits, Macedonia took his idea to developers at Pacific Northwest National Laboratory, operated by Battelle for the U.S. Department of Energy (DOE). Shortly thereafter, the DOE and the Department of Defense (through DARPA) agreed to put up $5 million to develop a 3-D ultrasound system for diagnosing battlefield injuries.

A MUSTPAC must

While conventional ultrasound is a 2-D imaging procedure, 3-D ultrasound was critical to the premise behind MUSTPAC—scanning a fairly large volume of the patient at a remote site by an unskilled operator and then transferring the data in a store-and-forward file transfer mode to a skilled diagnostician.

"The point of the 3-D is that it permits data to be collected by someone who knows a little anatomy, but doesn't know anything about how to interpret ultrasound images," explains Rik Littlefield, project manager at Pacific Northwest National Laboratory.

Littlefield notes that a classic ultrasound exam is performed by a technician viewing a real-time, 15-frame/sec image as he moves a probe around the body. Without that ability and without the knowledge of how to interpret those images and where to re-point his hand to see what he really needs to see, the operator can't perform the exam.

"What 3-D data collection permits is to collect perfectly useful data in a sort of blind snapshot mode," says Littlefield. "If you think someone might have a gallstone, obviously the person who collects the data has to know where the gall bladder is. But he doesn't have to know what angle to point the probe in order to image the duct at the right angle to take the measurements."

In the MUSTPAC, a specially-designed simulated probe looks, feels, and acts like a real ultrasound probe. Littlefield adds that once an image is stored in a 3-D dataset, it can later be reviewed either locally or remotely.

Fourth of July prototyping

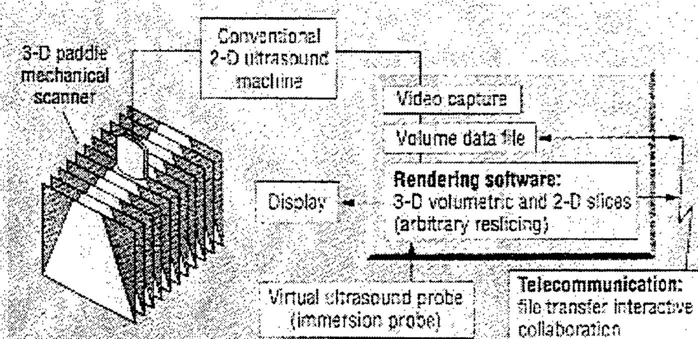
Once funding was approved for the project (that happened in April of 1996), development of the MUSTPAC proceeded at what had to be a rapid pace. Driving the team was a schedule that called for delivery of a prototype by early July.

Much like Macedonia's original design, MUSTPAC-1 designers built the unit around off-the-shelf components. The team also imposed a requirement that the system be transportable by a single soldier. "As an officer in the First Infantry Division in Germany, I clearly remember that the most useful equipment was that which one person could carry," notes Macedonia. "If it's small enough, it can go practically anywhere."

Anatomy of a telemedicine box

In its 85-pound backpack configuration, the first-generation MUSTPAC-1 supplies what's needed to acquire 3-D ultrasound data, visualize it locally, and transmit the data to a remote site for consultation in a teleconference. The MUSTPAC-1 is powered from a commercial uninterruptible power supply, using a battery, for about 45 minutes. It can also be powered from an ac line. The core of the system is a Hitachi Medical Systems Model EUB-905 2-D ultrasound subsystem.

The EUB-905 links to a Silicon Graphics Indy workstation by means of a 75-ohm video cable. Video-capture software feeds a 3-D dataset into a volume data file residing on the Indy's hard disk. Rendering software then permits operators to arbitrarily re-slice the 3-D dataset at any position or orientation using a stand-alone, joysticklike virtual ultrasound probe. Data is transferred to remote sites via a standard Ethernet connection. A stand-alone camera supports videoconferencing.



It was decided to make the system fit into a back pack. "That meant it clearly had to be under 100 pounds," recalls Littlefield. What the team ultimately designed weighed in at 85 pounds.

Close to 25 pounds of the total weight was attributable to the centerpiece of the system, an off-the shelf EUB-905 ultrasound subsystem from Hitachi Medical Systems (Tarrytown, N.Y.). Measuring 13.6 × 16 × 6.4 inches in size (34 × 40 × 16 cm) the compact 2-D unit offered a variety of display modes, as well as 192 channel probes, 256 gray-scale steps, and a high-frequency probe that operates at up to 10 MHz. It can also be powered off either a 120-V ac line or batteries.

"We picked the EUB-905 because it offered an excellent combination of image quality

"A Pentium portable with integrated keyboard will likely eliminate the bulk of the stand-alone keyboard"

and size and weight," explains Littlefield. Also important to the selection of the EUB-905 was that it had won Food and Drug Administration FDA 510(k) approval.

With future commercialization on their minds, MUSTPAC designers went out of their way to avoid customizing the subsystem. "We avoided like the plague breaking into that system," explains Littlefield. "Doing anything at all to it that could affect its performance would have voided the 510(k) approval."

Complementing the EUB-905 is a 3-D paddle electromechanical scanner. Compact and lightweight, the paddle was designed to be strong enough to support several pounds of longitudinal thrust and withstand pushing against a patient's body.

Weight versus Mips

The second heaviest component in the MUSTPAC-1 is its compute platform. For that element, the design team chose an Indy workstation from Silicon Graphics Inc. (SGI—Mountain View, Calif.). Built around a 64-bit MIPS R5000 microprocessor, the SGI workstation is optimized for compute-intensive

H-4

"3-D permits data to be collected by someone who knows a little anatomy, but doesn't know anything about how to interpret ultrasound images," explains Rik Littlefield, project manager at Pacific Northwest National Laboratory.

graphics and multimedia applications. The MUSTPAC design team picked a platform with a 2-Gbyte hard drive and support for seven SCSI-2 devices. The team then loaded it with 128 Mbytes of RAM to minimize disk accesses.

While bulkier than currently available laptops, the Indy was deemed a clear choice for MUSTPAC, as it offered video capture capabilities in a Unix environment. "We were considering some Pentium-based notebooks, but there was no way we were going to get the quality video capture we needed within the time frame we needed it," notes Littlefield. "What's more, since our visualization software already ran in Unix, we didn't have to do a port to Windows NT."

There were tradeoffs. One of the drawbacks to the Indy platform was that it required a stand-alone keyboard. "In theory, we could've done the whole thing with a touch panel," says Littlefield. "But we knew the users we were targeting wanted not just a 3-D ultrasound system, but a more general purpose platform." For future-generation MUSTPACs, Littlefield indicates a Pentium portable with integrated keyboard will likely eliminate the bulk of the stand-alone keyboard.

Since the Indy doesn't come with an integrated display, the MUSTPAC designers opted to add an SGI presenter panel to the backpack configuration. "We needed 1,024 × 1,280-pixel resolution with CRT-quality gray scale," explains Littlefield. "Physicians performing diagnosis at remote locations use a standard analog CRT."

Image objections

"A common gripe among doctors about ultrasound captured static images is you can't tell what you're looking at unless somebody tells you where the probe was pointed," explains Littlefield. "A standard joke is you can't tell the difference between an ovarian cyst and a gall bladder."

A problem for the MUSTPAC designers was the realization that trained ultrasound diagnosticians were used to working in a 2-D environment, not with a 3-D dataset. "Through years of training, doctors have developed great amounts of skill and hand-eye coordination in terms of being able to infer 3-D anatomy—based not only on where they think their hand is pointing right now, but also how an image changes as they move their hand," says Littlefield.

"Since the person doing the diagnosis wasn't going to be physically located with the patient, and wouldn't have direct control over the imaging," continues Littlefield, "we felt it was very important to give the operators a familiar interface that would permit them to exploit all their standard skills."

"It's kind of counter-intuitive," adds Macedonia. "People who aren't in medicine typically think, 'Gosh, it seems like a 3-D image would be a lot more useful than a 2-D image.' But the fact of the matter is that the experienced radiologist uses a 2-D image and does 3-D reconstruction in his or her head."

One answer to the visualization problem was sitting just down the hall in Littlefield's office. "One day I was mulling over how to solve this problem and I happened to walk through our multimedia lab," he remembers. "Sitting on the table was a fancy joystick, with XYZ pitch, roll, and yaw. What more natural thing to do than to simply let the software listen to that device and put the corresponding images up on the screen? We'll fake a real-time examination, I thought."

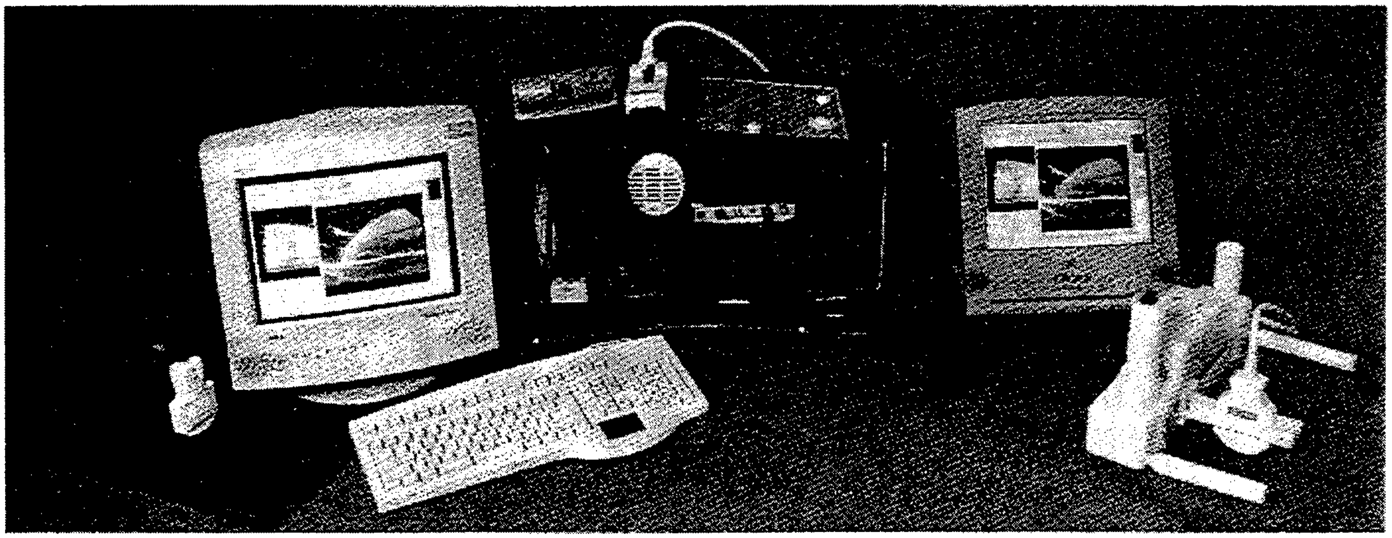
Out of that idea came a virtual ultrasound, or immersion, probe. Offering equivalent 6-D sensing capability (3-D position plus 2-D tilt and rotation), the probe—with the help of special volume-visualization software—can be used to re-slice the ultrasound information along arbitrary so-called cutting planes.

Software ain't easy

While the MUSTPAC-1 development project relied largely on off-the-shelf components to minimize design time, software was another story. Much of the innovative integration work for the MUSTPAC came about in software development.

The Fraunhofer Center for Research in Computer Graphics (CRCG—Providence, R.I.) played a key role. It's a non-profit computer graphics research group specializing in the study of volume visualizations, virtual environments, collaborative work tools, and user interfaces.

Researchers at the center modified TeleInViVo, 3-D ultrasound visualization software based on InViVo 3-D volume visualization code developed by Dr. Georgios Sakas at the institute's Darmstadt, Germany, facility. Featuring network collaboration tools for remote consultation and system control, TeleInViVo permits physicians to view a range of data sets, including CAT (computer-assisted tomography), MRI (magnetic resonance imaging), MRA (magnetic resonance angiography), and PET (positron emission tomography) scans. It also allows users to exchange and manipulate the data sets via ISDN or ATM net-



Weighing about 85 pounds, the MUSTPAC-1 includes an ultrasound system, a 3-D paddle, and a large LCD screen. A Silicon Graphics workstation-class Indy computer—with camera—completes the picture.

works. CRCG made modifications of the software to enable the use of the virtual ultrasound probe.

CRCG's software used position and orientation information derived by the probe to re slice the 3-D ultrasound data along arbitrary cutting planes. The screen image is updated in real time so that diagnosticians see the 3-D MUSTPAC scans as conventional 2-D images.

GUI anxiety

Concurrently with hardware and TeleInViVo integration, programmers at Pacific Northwest National Laboratory also wrote code to bring the system's components together. One of the more challenging aspects of this was writing video-capture software and a graphical user interface. "Making it run acceptably fast was an ongoing exercise in frustration," admits Littlefield.

For the video input side, MUSTPAC designers built their applications on top of VL, a library from SGI. But since VL didn't handle any functions on the output side, the team's programmers had to write custom code to glue the VL-based applications with the user interface. The latter was written in TCL, a language and support library that comes out of the X Windows world.

While the actual amount of code proved relatively small, the task of managing the video input, as well as handing off the imagery to TCL for display on the screen and as a backdrop for the user interface, proved to be a very difficult task. "TCL is designed to use an event loop philosophy; it provides an event handler of its own," Littlefield explains. "SGI's VL is also designed to use the event-loop philosophy, but it uses an event loop of its own. Getting those two glued together so that all the events on both video input and X Windows sides were properly interleaved turned into a matter of several weeks of hair tearing."

No batteries included

Power-supply issues were also critical. At first, operating power was not a concern for the design team. Intended for use in armed forces Mobile Army Surgical Hospital (MASH) units, the MUSTPAC-1 was initially designed to operate from a standard 120-V ac power line. However, in the interest of making the unit truly useful in combat, the system also needed a battery-powered option. It was supplied with an off-the-shelf, 30 lb uninterruptible power supply. "The MUSTPAC is sufficiently low power that we could get 45 minutes of continuous operation off a standard UPS system," says Littlefield.

Similarly, the system's communications options were significantly narrowed when initial requirements called for its use with established Signal Corps connections. "They said, 'Look, we'll just give you a 10Base-T connection talking TCP/IP.' We said, 'Great,'" retells Littlefield. But down the road, Littlefield's designers still see an opportunity—particularly if the system is brought to commercialization. They want to add RF wireless capability in future iterations of the design. Littlefield sees RF satellite links, such as those based on the Immarsat birds, as the most likely scenario for this. Dual-mode cellphone technology is also feasible, he says.

Tuzla-tested

The MUSTPAC-1 prototype was shipped in July of 1996, but its first real-world trial came a month later when Macedonia took the system to the 212th MASH at Camp Bedrock in Tuzla, Bosnia. Concerns about reliability were quickly put to rest when Macedonia went to unload the system after it took a truck ride down a seven mile road called Crater Alley. To his dismay, Macedonia found the system had bounced off its palette and was lying in a corner of the back of the truck. "It had the crap kicked out of it," he unabashedly declares.

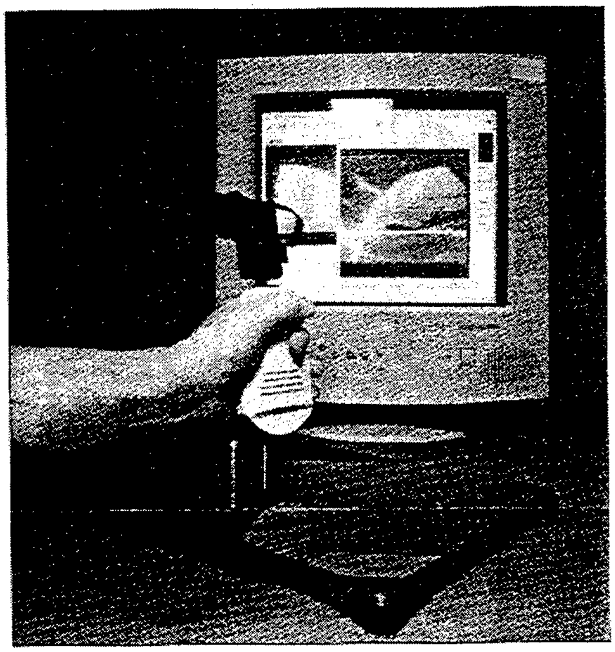
But the unit didn't fail. Once set up at MASH headquarters, the system was fired up and linked to the Army's local 10base-T Ethernet network. Data was transmitted back through a microwave link to a base miles away and then fed through a Ku-band

satellite link to another MUSTPAC unit in Landstuhl, Germany. That field test proved clearly that data could be collected and transmitted by personnel inexperienced with ultrasound technology.

"I initially thought I was going have to do all the scans," recalls Macedonia. "But when I got there, everyone asked to try it. Eventually, we had a medic, a Russian nurse, and even a chaplain try it out." The ability of diagnosticians to use the virtual ultrasound probe also exceeded expectations. "It became very clear it didn't matter who was doing a scan," recounts Macedonia.

Some of the results of the trip were completely unexpected. "We went into Bosnia thinking we were taking in a 3-D ultrasound machine and came out of the experience realizing we had what could be called a portable telemedicine system—that at its core had ultrasound," avows Macedonia.

Since the system does frame capture, users at the MASH quickly began experimenting with CCD cameras and other instruments to capture eye exams, ear exams, and even dental exams. They were anxious to send them in a store-and-forward fashion back to the rear. "The people at the MASH taught us that it's really a portable telemedicine system that allows you to examine a patient from the top of their head to bottom of their feet," jocularly notes Macedonia.



Users with little ultrasound training can collect data for remote analysis using the MUSTPAC-1 backpack telemedicine system.

A lighter future

At the moment, the MUSTPAC design team is focusing on reducing system weight and cost; a new-generation system is in the works. Key to achieving the goal will be a migration to a lighter and more compact Pentium-based platform that will include keyboard, display, and processor in a single unit. "That should eliminate about 10 pounds," believes Littlefield. "It'll eliminate a bunch of cable and separable interconnect problems as well."

"The development's a continuous evolution," concludes Macedonia. "I don't see an end to the MUSTPAC-1 project until we create a handheld—not a backpack—that allows me to have a look at people's bodies and figure out what's going on inside."

For more information...

Battelle/Pacific Northwest National Laboratory
Richland, WA
(509) 375-3776
Circle 155

Hitachi Medical Systems
Tarrytown, NY
(914) 524-9711
Circle 156

Silicon Graphics
Mountain View, CA
(408) 960-1980
Circle 157

The Fraunhofer Center for Research in Computer Graphics
Providence, RI
(401) 454-7490
Circle 158

APPENDIX I

Appendix I: *"Backpack remote medicine proves its worth"*, Jane's International Defense Review, February 1997

Reprinted with Permission from Jane's Information Group.

Backpack remote medicine proves its worth

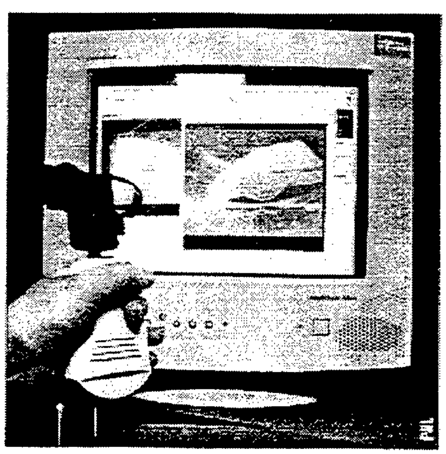
A portable telemedicine system providing ultrasound facilities for use in field hospitals has undergone successful trials with the US Army in Bosnia. Pacific Northwest Laboratory (PNL) developed the Medical UltraSound, Three-dimensional and Portable with Advanced Communication (MUSTPAC) system under a rapid-prototyping contract from the US Defense Advanced Research Projects Agency. The design exploits existing technology to make referral and diagnosis easier in the field, leading to improved patient care and a reduction in the number of unnecessary evacuations.

PNL says that MUSTPAC is unique in that it is effective, requires very little training, does not need a highly skilled operator at the patient's side, and operates well even in a low-bandwidth store-and-forward file-transfer mode. The laboratory is developing a production-standard version that is lighter, more compact, and uses different computer hardware.

MUSTPAC consists of a field unit installed in a backpack, allowing it to be operated as far forward as battalion aid stations, together with a separate virtual ultrasound probe and high-resolution color monitor. In its prototype form, the backpack contains a 'three-dimensional [3-D] paddle' electromechanical scanner; Silicon Graphics Presenter flat-panel display; Hitachi EUB-905 ultrasound machine; Silicon Graphics Indy computer; teleconferencing video camera; and keyboard with integral touchpad. The separate Immersion Probe — a virtual ultrasound probe — provides expert diagnosticians with a familiar interface that is easy to learn and to use.

The system permits on-the-spot visualization of internal bleeding, damage to solid organs, and penetrating injuries. It operates by scanning a fairly large volume of the patient at one time, so that diagnosis during the scan is not required. The operator places the scanner on the patient's abdomen for about 10s, while the system acquires a large volume of 3-D data. This requires minimal training. US Marine Corps Capt (now Maj) Christian Macedonia, the MUSTPAC Principal Medical Investigator, talked a Russian nurse through the process, via an interpreter, in about 5min during trials in Bosnia.

The equipment also provides a remote diagnostician with a familiar interface. The 'virtual ultrasound probe' consists of a modified Immersion Probe or an equivalent 6-D sensing capability (3-D position, 2-D tilt, and rotation). TeleInViVo visualization software developed by the Fraunhofer Center for Research in Computer Graphics uses probe position and orientation inputs to 'reslice' the 3-D ultrasound data along arbitrary cutting planes. The screen view is updated in real time (5–10 times a second), so that diagnosticians can work with MUSTPAC 3-D scans in the same way that they would with a real patient and a conventional 2-D ultrasound system.



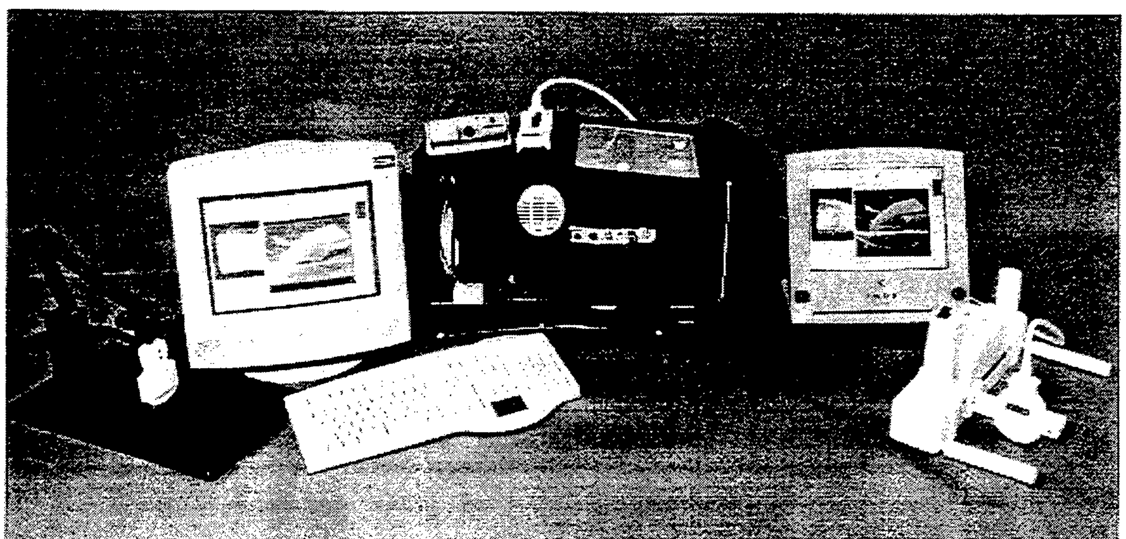
Consulting physicians on another continent can use MUSTPAC's virtual-reality technology to obtain 2-D diagnostic views from 3-D ultrasound data. An Immersion Probe provides high-resolution pictures of scans taken elsewhere.

PNL delivered the MUSTPAC-1 prototype to the US Army Medical Research and Materiel Command's Medical Advanced Technology Management Office in July last year. Following a series of pre-deployment evaluations supervised by the Center for Total Access at Fort Gordon, it was shipped to Landstuhl in Germany. In early August the equipment began a month-long deployment with the 212th Mobile Army Surgical Hospital at Camp Bedrock in Tuzla, Bosnia. It transmitted data through a microwave link to Eagle Base, 12km away, and then fed through a Ku-band satellite link to another MUSTPAC unit in Landstuhl. Four other receiving sites were situated in the US.

The MUSTPAC-1 prototype weighs just under 40kg. The production-standard version now under development will be more compact, weigh about 27kg, and incorporate a laptop computer in place of the Indy unit. The equipment may then enter limited production under a government/industry partnership. Potential users include rapid-reaction forces and naval units.

In the latter case, MUSTPAC could assist in detecting gallstones, diagnosing kidney disease, and meeting the need for gynecological care that has resulted from the deployment of women aboard warships. The system could also form an adjunct to image-directed surgery for immediate treatment. MUSTPAC could show the position of both injuries and surgical instruments, supporting tasks such as the injection of glue to stitch internal wounds. **MH**

The MUSTPAC-1 prototype consists of a virtual ultrasound probe (extreme left of photograph), high-resolution color monitor (next to the probe), and a backpack (center) containing the other elements. These comprise an electromechanical scanner (extreme right), flat-panel display (next to it), ultrasound machine and its associated computer (both in backpack), teleconferencing camera (on backpack), and keyboard with integral touchpad (foreground).



APPENDIX J

APPENDIX J: "*3-D Ultrasound for Physiological Monitoring*", presentation slide set from the DARPA Ultrasound Workshop, Lansdowne, VA, February 11-13, 1998.

Real Time 3-D Ultrasound For Physiological Monitoring

Project # DAMD17-94-C-4127

Richard J. (Rik) Littlefield, Battelle, P.I.

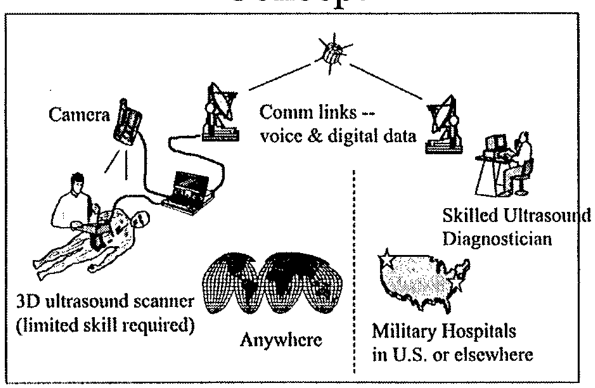
DARPA Ultrasound Workshop, Lansdowne, VA
Feb.11-13, 1998

•Project Focus

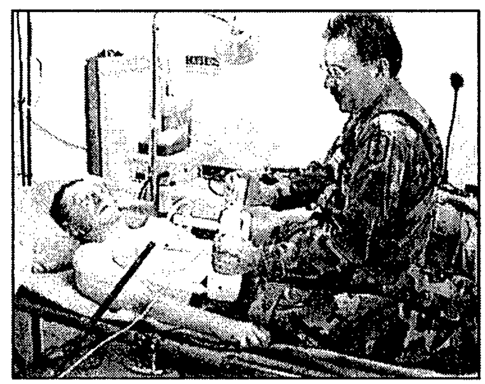
3-D ultrasound telemedicine (tolerating limited connectivity, exploiting store-and-forward)

Integrated system development and technology demonstration.

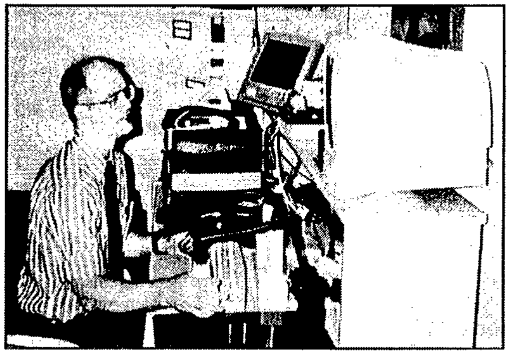
3-D Ultrasound Telemedicine Concept



Scanning



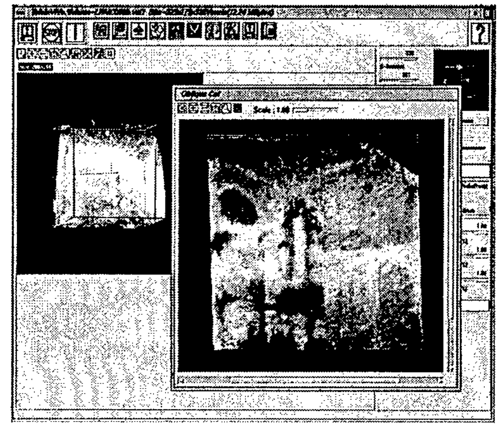
Diagnosing



J-3

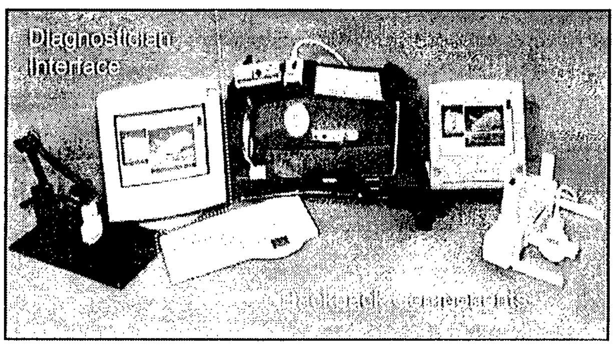
Appendix J, Slide 5

Diagnostic Screen (human liver)



Appendix J, Slide 6

MUSTPAC-1 System



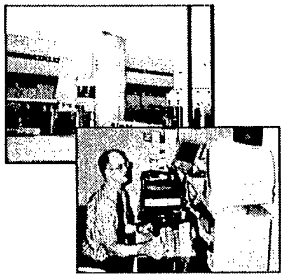
Appendix J, Slide 7

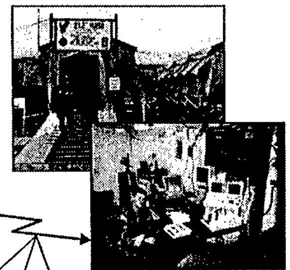
MUSTPAC-1 Main Points

- Medical UltraSound, Three dimensional, Portable, Advanced Communications
- Telemedicine focus
- Effective remote ultrasound exams
- No diagnostic expertise needed to scan
- Familiar diagnostic interface
- Prototype units fielded in August 1996

Appendix J, Slide 8

Field Trial





LRMC
Landstuhl, Germany

212th MASH
Tuzla, Bosnia

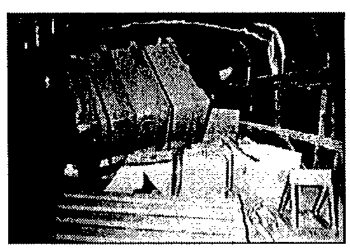
MAMC (Tacoma), GU (Wash DC), CRCG (Providence RI)

Results

- Focused on usability in field environment
- Informal evaluation
  - 75 scans, 10 diagnosticians, 20 scan operators
- Ease of use: very good
  - Diagnostician trainup times: 5 minutes typical (due to virtual ultrasound probe)
  - Scanner training: operational only (1/2 hour typical)
- Acceptance:
  - very good, improving with hands-on experience

•More Results

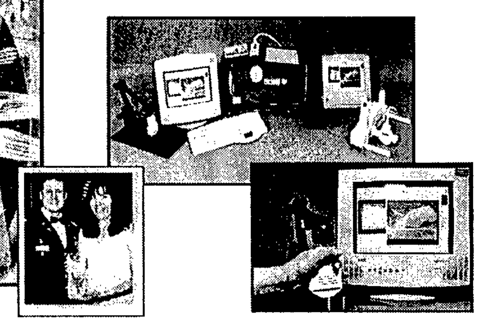
- Versatility: very good
  - network connectivity
  - image transfer
  - text messaging
- Robustness:
  - surprisingly good



•Arrival in Tuzla -- bounced upside down on Crater Alley

1997 Discover Award

Computer Hardware and Electronics
MUSTPAC 3-D Ultrasound System



•Application Targets

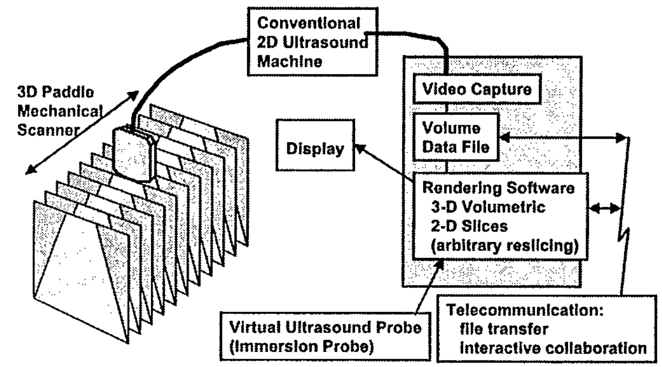
Military
- Navy [Bakelar, committed]
- MRMC/TATRC

Civilian
- McKennan Hospital (South Dakota) [Helmbrecht, proposed]

International
- Ukraine/Chernobyl thyroid screening [Satava/Cheban, proposed]
- prostate screening/monitoring [Macedonia/Tanahashi, investigating]

Special situations
- Everest expedition [Satava/Bruton, committed]

MUSTPAC-1 Principles of Operation



•Major Components of MUSTPAC-1

Silicon Graphics Indy & Presenter
- (computer & display)

"3D Paddle" scanner

Virtual Ultrasound Probe

TeleInViVo software (Fraunhofer CRCG)

Data capture, transfer, and UI software

Hitachi 905 ultrasound engine

•Modifications Needed For MUSTPAC-2

Pentium computer replaces SGI

"3D Paddle" scanner

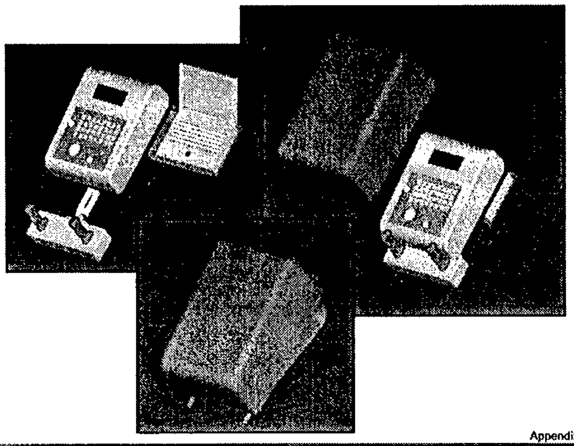
Virtual Ultrasound Probe

TeleInViVo software (Fraunhofer CRCG)

Data capture, transfer, and UI software

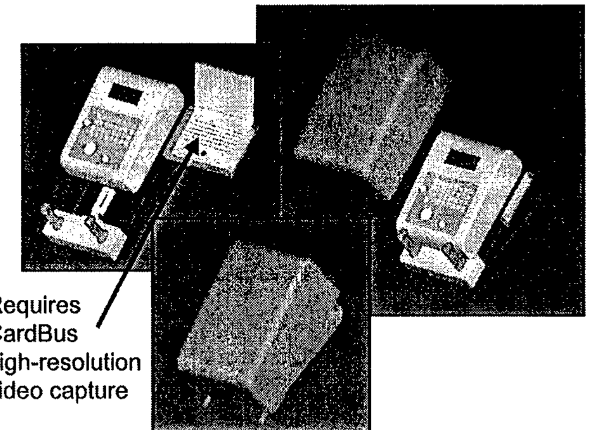
Hitachi 905 ultrasound engine

Early 1997 Packaging Concept



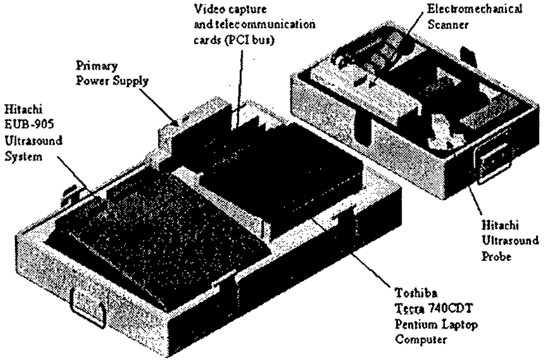
Appendix J, Slide 17

Early 1997 Packaging Concept



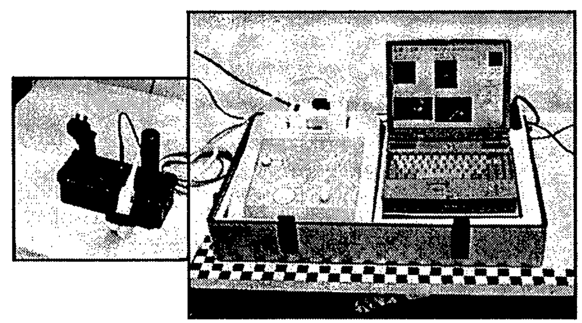
Appendix J, Slide 18

Mid 1997 Packaging Plan



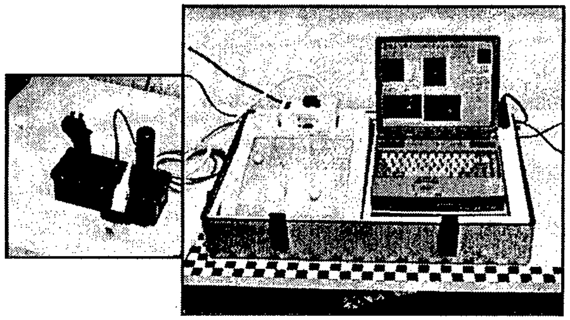
Appendix J, Slide 19

Prototype System -- October 1997



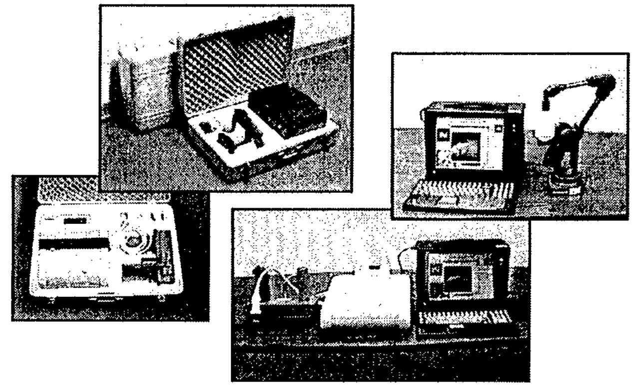
Appendix J, Slide 20

Prototype System -- October 1997

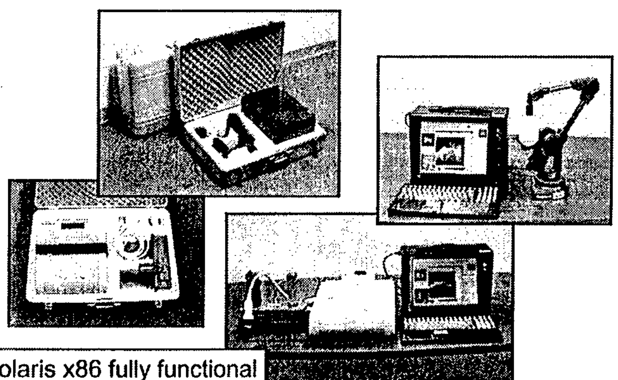


Too heavy to justify expense of custom packaging.

Revised Prototype -- February 1998



Revised Prototype -- February 1998



Solaris x86 fully functional
Windows/NT in unit test

•Military Demo 1998

Phase 2: Navy carrier deployment, 4Q98

Phase 1: Develop and evaluate at National Naval Medical Center, Bethesda

- integrated team of physicians (radiologists, surgeons, OB/GYN) and technicians
- evaluate usefulness
- develop and package scanning procedures
- identify and train users on both ends
- extend system as needed (RadCom and communications compatibility, dataset compression, freehand scan)

3-D Dataset Compression

7.58 MB lossless (12.6 MB raw) — 1.26 MB, JPEG

At 56 KB: 18 minutes — 3 minutes

•Summary

MUSTPAC development proceeding

Military demo scheduled

Significant interest by several applications

APPENDIX K

APPENDIX K: ***"MUSTPAC 3-D Ultrasound Telemedicine – The MUSTPAC™ System", Web site*** **http://aims.pnl.gov:2080/MUSTPAC-2/index.html*****, as of October 26, 1999.***

MUSTPAC

3-D Ultrasound Telemedicine -- The MUSTPAC™ System

Summary

MUSTPAC™ (Medical UltraSound, Three-dimensional and Portable, with Advanced Communications) is a telemedicine system based on 3-D ultrasound data acquisition.

MUSTPAC™ provides the unique capability of allowing an effective ultrasound examination to be performed remotely -- with no diagnostic skills needed by the operator at the patient's location, and no need for a dedicated videoconference link.

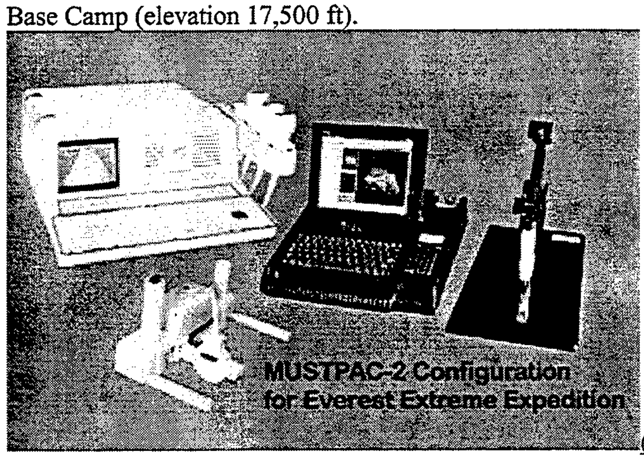
The MUSTPAC™ technology is being developed at the Pacific Northwest National Laboratory in support of the Advanced Biomedical Technologies program at the Defense Advanced Research Projects Agency (DARPA)

Currently, the MUSTPAC-2 system is an investigational device being evaluated in both clinical and field environments.

Highlights as of May 1998 include:

- A ruggedized MUSTPAC-2 system is being used by the Everest Extreme Expedition to collect scientific data on physiological adaptations to high altitude. The system on Everest incorporates a Fieldworks FW7666P rugged laptop and an Ausonics Impact VFI portable ultrasound scanner with Doppler capability. This system

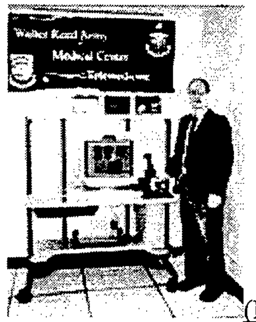
MUSTPAC-2 configuration accompanying the Everest Extreme Expedition to Base Camp (elevation 17,500 ft).



(Bigger picture)

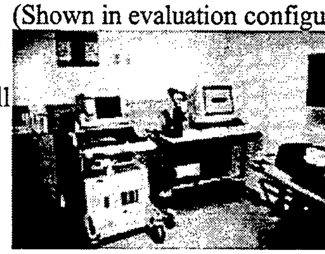
is supported by diagnostic workstations located at Walter Reed Army Medical Center and Yale University.

MUSTPAC-2 diagnostic workstation at Walter Reed Army Medical Center Telemedicine.


(Bigger picture)

- A standard MUSTPAC-2 system has been installed at the National Naval Medical Center (Bethesda), where it will undergo clinical evaluation in preparation for shipboard testing later this year.

MUSTPAC-2 system in Radiology Department of National Naval Medical Center. (Shown in evaluation configuration with ATL HDI ultrasound scanner.)


(Bigger picture)

For more information...

Several detailed documents are available describing the current MUSTPAC-2 system and its predecessor MUSTPAC-1:

- System design and experiences of the MUSTPAC™ family of systems are described in a 7-page paper titled "MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System", presented at the 1998 IEEE International Ultrasonics Symposium, Sendai, Japan (Oct.6-8). This paper is available as a Microsoft Word file.
- A two-page summary handout, from the DOE Biomedical Technologies Exposition, March 21, 1999, is available as a Microsoft Word file.
-
- A large photomontage marketing graphic is available as a JPEG file.
- System design and field experiences of the MUSTPAC-1 are described in a 5-page report titled "MUSTPAC-1: 3-D Ultrasound Telemedicine Tool for Deployment Situations in Bosnia and the European Theater". This report is available in HTML and with higher quality graphics as a Microsoft Word file.
- An earlier description of the MUSTPAC-1, dated December 1996, is also available.
- A December 1997 briefing presentation, describing the MUSTPAC-2 system with application to civilian health care, is available as a Microsoft PowerPoint file.
- A February 1998 presentation given at the DARPA ultrasonics workshop also is available as a PowerPoint File.

APPENDIX L

APPENDIX L: "*MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System*", 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, October 5-8, 1998.

Reprinted with permission.

Paper #PJ-2, 1998 IEEE International Ultrasonics Symposium, Sendai, Japan, Oct 5-8, 1998.

MUSTPAC™ 3-D Ultrasound Telemedicine / Telepresence System

Richard J. Littlefield
Pacific Northwest National Laboratory, P.O.Box 999, Richland, WA 99352
Email: rj_littlefield@pnl.gov

MAJ Christian R. Macedonia, MD†
Dr. John D. Coleman‡

Abstract — MUSTPAC™ is a family of ultrasound telemedicine systems based on the use of 3-D (volumetric) data acquisition. Diagnostically useful scans can be taken by an operator with limited training and no ultrasound diagnostic skills, using a simple "point-and-shoot" procedure. For diagnosis, volumetric datasets are transmitted to a remote radiologist, who uses a "virtual ultrasound probe" to reslice the datasets along arbitrary planes, using familiar hand movements and seeing 2-D (planar) displays similar to those of a conventional real-time hands-on examination. Prototype MUSTPAC™ systems have operated in a military field hospital and on a Mt. Everest climbing expedition, and are currently being evaluated for clinical application in rural and remote environments.

INTRODUCTION

Health-policy experts have become increasingly concerned about the uneven distribution of physicians. The lack of widespread availability of expertise in diagnostic ultrasound has been a particular problem, causing some to advocate the creation of ultrasound "centres of excellence".[1] Recently, a number of groups have pioneered realtime remote ultrasound examination and have shown the value of teleconsultations for ultrasound technicians in rural areas.[2,3, 4]

However, conventional realtime 2-D (two-dimensional) ultrasound imaging has the significant drawback that a highly skilled operator must be physically present at the patient's location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to position the image acquisition probe at the correct location and orientation.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe to locate the gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient's internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing introduces some difficulties in using conventional 2-D ultrasound in a telemedicine setting, where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound potentially allows diagnostically useful scans to be taken by an operator with limited training, no diagnostic skills, and no real-time expert assistance. This is accomplished by having the system scan a fairly large volume of the subject's anatomy at one time, without interpretation, so that the operator can use a simple "point-and-shoot" strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that includes the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done later by an ultrasound expert located elsewhere.

Beginning in 1996, a series of prototype 3-D ultrasound telemedicine systems has been developed to demonstrate and evaluate this telemedicine concept. These systems, called MUSTPAC™ (Medical UltraSound, Three dimensional, Portable, with Advanced Communications), have been tested in a variety of environments, including a U.S. Army telemedicine network in Europe[5], a Mt. Everest climbing expedition, and several medical institutions in the U.S. Clinical studies are currently underway to evaluate MUSTPAC™ for routine application in rural and remote settings.

This report discusses the design, implementation, and use of several MUSTPAC™ systems.

† U.S. Army Medical Corps, Georgetown University Medical Center, 3800 Reservoir Road, Washington, DC 20007
‡ Fraunhofer Center for Research in Computer Graphics (CRCG), 321 S. Main Street, Providence, RI 02903

OVERVIEW

MUSTPAC™ is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation. It is designed to work in a telemedicine framework, enabling diagnostically useful ultrasound scans to be taken by an operator with no diagnostic skills, modest training, and no online connection to an expert.

Typically a MUSTPAC™ system is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across his/her skin over the area of interest (Figure 1). During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric dataset of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.

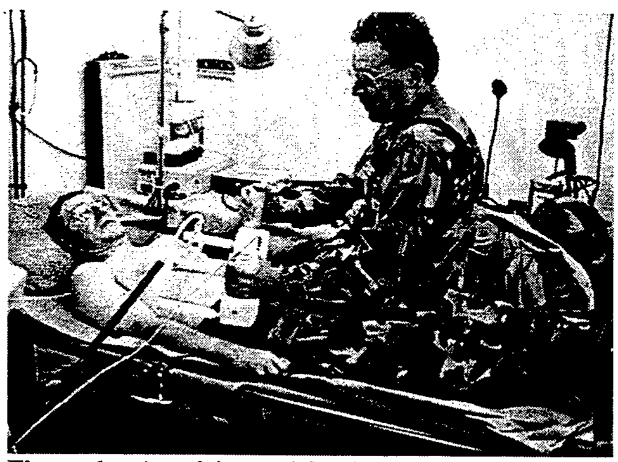


Figure 1. Acquiring a 3-D abdominal scan using a linear scanning device and conventional ultrasound transducer.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician.

Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D dataset simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity (Figures 2-4).

Figure 2. Interpreting a 3-D scan using the Virtual Ultrasound Probe at a diagnostic workstation.

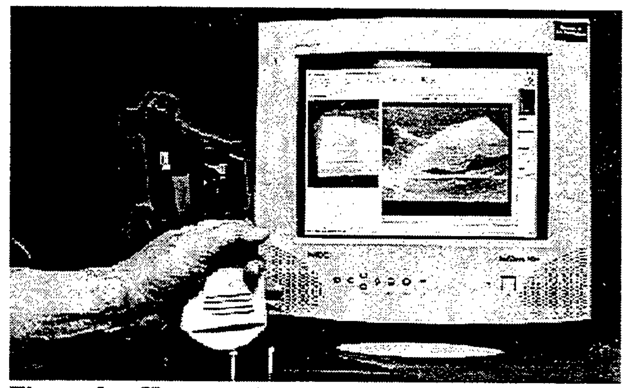


Figure 3. Closeup of the Virtual Ultrasound Probe and diagnostic workstation display. Image on the screen is of a plastic phantom.

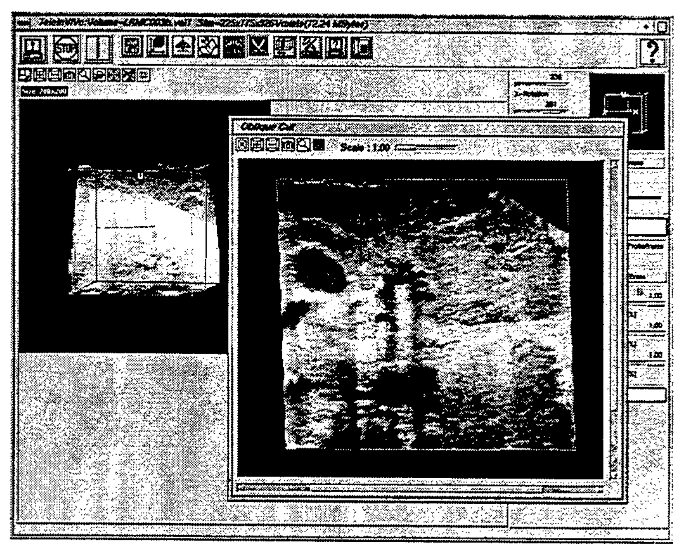


Figure 4. Actual diagnostic display (human liver with clotting in major vessels).

PRINCIPLES OF OPERATION

All versions of the MUSTPAC™ system developed to date have used a similar high level design (Figure 5). There are two primary operations — scanning and visualization — typically separated by a data transmission step.

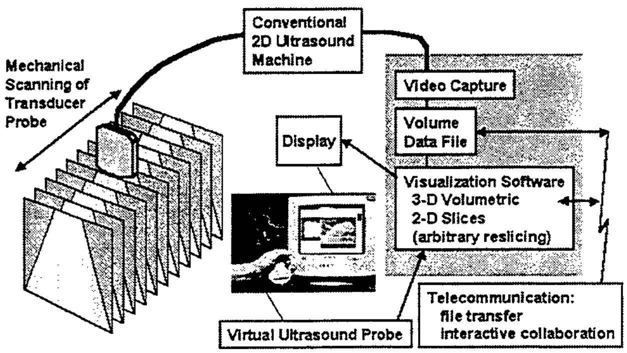


Figure 5. Major aspects of the MUSTPAC™ architecture. In this diagram, scanning and visualization are shown on the same system. In practice, these two functions would normally be done on two systems.

Scanning

Volumetric scanning in MUSTPAC™ is done using the well-known approach[6] of mechanically moving the transducer probe of a conventional off-the-shelf ultrasound machine. As the probe moves, the ultrasound machine generates a sequence of video images, called B-scans, showing 2-D slices of the subject under the probe. A computer digitizes the sequence of B-scan images and corresponding spatial positions of the transducer probe, then assembles the B-scans to form a 3-D volumetric dataset that represents a sort of "snapshot" of the subject's anatomy. Anatomical movement is not captured, except in the form of motion artifacts that the diagnostician must learn to ignore.

MUSTPAC™ supports two types of volumetric scanning: linear and freehand. In linear scanning, a hand-held motor-driven device is used to move the transducer in a straight line, at a constant speed, keeping the transducer oriented perpendicular to the direction of movement. This generates a set of parallel registered images that naturally assemble to form a dense rectangular 3-D dataset. Linear scanning is fairly restrictive in what anatomy it can be used with. However, the technique generates very high quality datasets because tightly controlling the transducer position essentially eliminates the possibility of position error and gaps in the image data.

In freehand scanning, the transducer is hand-held and moved by the operator. A 6-degree-of-freedom sensor attached to the ultrasound transducer records its position and orientation. Software in the MUSTPAC™ system then reconstructs a dense 3-D volumetric dataset by interpolating as necessary between the somewhat random planes of acquired image data. This procedure generates somewhat lower quality datasets, primarily due to inaccuracies in sensing the probe position. The quality of freehand datasets depends to a considerable degree on properties of the position sensor and its interaction with the operating environment. The MUSTPAC™ development group is currently evaluating the tradeoffs between free-space magnetic sensors (such as the Ascension[1] pcBIRD™) and mechanical articulated arms (such as the Immersion[2] MicroScribe-3D™).

Scans are usually taken at 15 fps (frames per second) at a scanning rate of 1 cm/sec, using a 3.5 MHz or 5 MHz convex-face sector-scan probe. With typical penetration depths, this results in scanning a region 4-6 cm wide at the skin surface and 20 cm wide at 15 cm deep, with a voxel (volume element) size of roughly 0.7mm on each axis. The resulting 3D rectangular dataset contains about 13 million voxels.

Visualization for Analysis and Diagnosis

The primary function of visualization in MUSTPAC™ is to allow experienced sonologists to make diagnostic decisions. Thus, the emphasis is on providing to those diagnosticians a user interface that is familiar, easy to learn, and productive.

Screen displays. The primary visualization tool in MUSTPAC™ is TeleInViVo™[3]. TeleInViVo™ can generate several kinds of images:

- 2-D slices at arbitrary positions and orientations.
- 3-D volumes using "maximum intensity projection" (MIP) and similar techniques for combining the values of dataset volume elements (voxels).
- 3-D surfaces defined by threshold values and rendered using one of several shading techniques

In MUSTPAC™, the most common practice is to combine a large 2-D slice image with a small 3-D volumetric image (Figure 4). The 2-D slice shows detail that is diagnostically useful, while the 3-D volumetric image provides context by showing location of the 2-D slice within the volume.

Virtual Ultrasound Probe. To provide diagnosticians with a familiar, convenient user interface, the MUSTPAC™

---

[1] Ascension Technology Corp., Burlington, VT, http://www.ascension-tech.com

[2] Immersion Corp, San Jose, CA, http://www.immerse.com

[3] Fraunhofer CRCG, Providence, RI, http://www.crcg.edu

version of TeleInViVo™ has been extended by the addition of a Virtual Ultrasound Probe (Figure 3). This is a hand-held 6-D input device combined with software to control 2-D slicing of volumetric datasets in the same way that a real ultrasound probe controls 2-D imaging of patients. That is, the Virtual Ultrasound Probe looks, feels, and acts like a real ultrasound probe in that the on-screen image is constantly updated in real time (typically 5-10 times per second) to reflect the position and orientation of the probe. (Again, this real time updating does not reflect anatomical movement, which is not captured in the datasets.)

Data Transmission

The MUSTPAC™ system provides two major methods of data communication: batch mode file transmission and TeleInViVo™ incremental transmission.

In batch mode file transmission, 3-D datasets and associated files are transferred using the Internet standard "ftp" protocol. If bandwidth is limited, then the 3-D datasets are compressed before transmission, using standard JPEG[4] methods. On typical datasets, this achieves approximately 10X compression without visible effect on the images.

Incremental communication capabilities are also built into the TeleInViVo™ visualization program. These capabilities allow all or part of the full dataset to be transferred quickly at reduced resolution, while the user interactively evaluates the images. This feature has not been used extensively to date, but is expected to become more frequent as MUSTPAC™ systems are incorporated into consulting practices. Typical use is envisioned to be transfer of the entire dataset with resolution reduced by 4X per axis (64X overall), followed by transmission of an identified region of interest at the full resolution of the dataset.

IMPLEMENTATIONS

MUSTPAC-1

In the summer of 1996, the first prototype system was developed for testing by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was designed to demonstrate an ultrasound telemedicine system in a backpack.[7,8]

System components and packaging. Major components of the MUSTPAC-1 are shown in Figure 5. These components include (right-to-left):

- Battery-powered linear scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display.
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)
- Keyboard with integral touchpad.
- High-resolution color monitor.
- Virtual Ultrasound Probe
- TeleInViVo™ visualization software.
- Other custom data acquisition and control software.

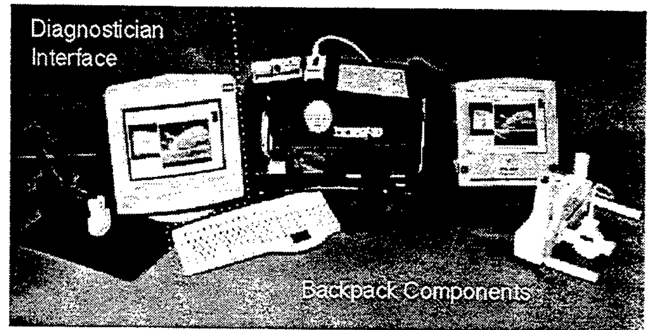


Figure 5. MUSTPAC-1 system components as packaged for military field evaluation.

Field Experiences. In August, 1996, the MUSTPAC-1 system was deployed by the U.S. Army to the 212th Mobile Army Surgical Hospital in Tuzla, Bosnia. A second MUSTPAC-1 placed at the Army's Landstuhl Regional Medical Center in Germany served as the primary receiving station.

Scanning. During the deployment, a total of 72 scans were performed. Most of these scans were taken by operators with no ultrasound diagnostic skills and minimal MUSTPAC-1 training (typically 10 minutes). No formal evaluation of the image quality was performed; informal evaluation by a variety of experienced ultrasound users suggested that the quality of the scans was largely independent of an operator's level of training and generally ranged from adequate to good.

Communications. Most transfers between Bosnia and Germany were performed using ftp over a roughly 1 megabit/second geosynchronous satellite link leased by the Army. Despite a round-trip packet delay of 580-600 ms, net transfer rates of roughly 50 Kbytes/second were routinely achieved. Thus typical 3-D datasets of 6-12 Mbytes required only a few minutes to transfer even without compression.

As exercises, 3-D datasets were also transferred over two slower communication links. One of these links was between Germany and Washington DC (USA) at 56 Kbits/sec using the International Maritime Satellite System (INMARSAT) and its associated telephone system ISDN link. The other was between Bosnia and Germany using

[4] Joint Photographic Experts Group, ftp://ftp.uu.net/graphics/jpeg

the Army's Tactical Packet Network (TACNET) at 9.6 Kbits/sec. These transfers were also successful, but would have been too slow for routine use. (Data compression was added to the MUSTPAC-2 to address this deficiency.)

Diagnostic Usability. During the Bosnia deployment and in the 6 months after its completion, the MUSTPAC-1 system was operated by approximately 20 experienced ultrasound users. Again, informal evaluation suggested that the system was very easily learned. One striking observation was that no experienced ultrasound user required more than 5 minutes practice with the Virtual Ultrasound Probe to begin making medical interpretations of 3-D scans that he/she had not previously seen.

MUSTPAC-2

MUSTPAC-2 is actually a family of MUSTPAC™ systems implemented on a common base of Intel Pentium processors using the Windows/NT operating system. The principles of operation are similar to MUSTPAC-1. However, MUSTPAC-2 incorporates several significant improvements from the user's standpoint. These include:

- Simplified and more robust user interface
- Wider range of packaging options (e.g. lightweight and rugged data acquisition system versus high performance diagnostic workstation)
- Increased network compatibility.
- Faster transmission and reduced data volume (through JPEG data compression).
- DICOM v3.0 import/export capability[5].
- Freehand scan (research quality – still under development for routine clinical use).

Several configurations of MUSTPAC-2 systems have been developed for specific purposes. These purposes include:

- Everest Extreme Expedition
- Hospital clinical evaluation
- Remote clinic consultation

Everest Extreme Expedition. An unusually rugged portable configuration of MUSTPAC-2 (Figure 6) accompanied the Yale/NASA telemedicine team on the May 1998 Everest Extreme Expedition[6] to Base Camp (elev. 17,500 ft). 3-D ultrasound datasets were transmitted back to MUSTPAC™ diagnostic workstations at Yale University (New Haven, CT) and Walter Reed Army Medical Center (Washington, DC) for interpretation. In addition, the MUSTPAC™ system acquired a series of 2-D images containing spectral Doppler data characterizing blood flow in major arteries, as part of a scientific study of climber adaptations to high altitude.

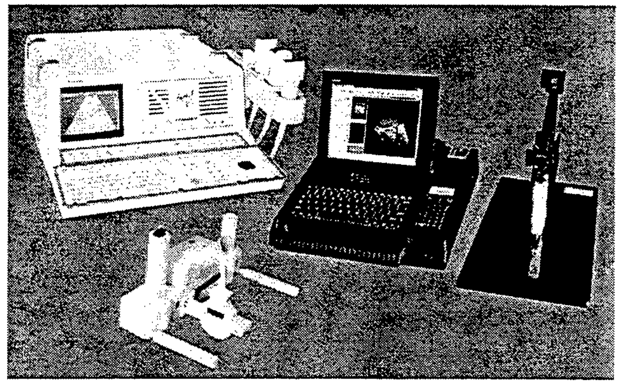


Figure 6. MUSTPAC-2 Everest Extreme configuration. This system incorporated a 166 MHz FieldWorks FW-7666P computer[7] (center), Ausonics Impact VFI ultrasound machine[8] (upper left), MUSTPAC-1 battery powered linear scanner, and MUSTPAC-1 Virtual Ultrasound Probe.

Hospital clinical evaluation. A deskside system (Figure 7) equipped for both scanning and visualization has been installed at the National Naval Medical Center (NNMC) in Bethesda, MD. This system is being evaluated for use in a clinical setting, prior to possible shipboard deployment.

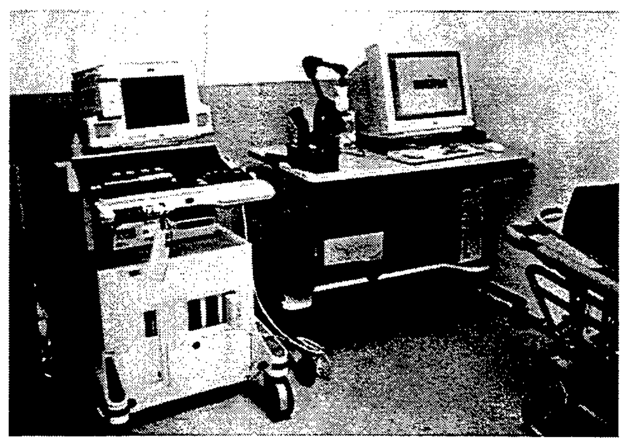


Figure 7. MUSTPAC-2 clinical evaluation system at NNMC. This unit incorporates a 333 MHz Dell Dimension XPS computer[9] (under desk), MUSTPAC-2 Virtual Ultrasound Probe based on the Microscribe 3D articulated arm[10] (on table), MUSTPAC-2 linear scanner (on table), and NNMC's existing ATL HDI-3000 ultrasound machine[11] (console and cabinet at left).

[5] Merge Technologies, Milwaukee, WI, http://www.merge.com

[6] http://www.explorers.org/newsfiles/e3.html

[7] Fieldworks Inc., Eden Prairie, MN, http://www.field-works.com

[8] Universal Medical Systems, Bedford Hills, NY, http://www.u-m-s.com

[9] Dell Computer Corporation, Round Rock, TX, http://www.dell.com

[10] Immersion Corporation, San Jose, CA, http://www.immerse.com

[11] ATL Ultrasound, Bothell, WA, http://www.atl.com

Remote clinic consultation. The "lunchbox" configuration (Figure 8) focuses on data acquisition, with limited capability for visualization. This demonstration/evaluation unit represents a configuration being considered for installation in a network of telemedicine clinics in rural northern U.S.

Figure 8. This portable "lunchbox" configuration incorporates a 166 MHz BSI LCD V8 computer[12], MUSTPAC-2 linear scanner (not shown), MUSTPAC-2 Virtual Ultrasound Probe, and any of several existing ultrasound machines (also not shown).

DISCUSSION

Experience to date suggests that MUSTPAC™ is a promising approach for extending the application of ultrasound in telemedicine. Further studies are needed, however, to determine its usefulness in clinical practice. In addition, MUSTPAC™ has a number of recognized limitations that need to be addressed. These include:

- *No Doppler imaging.* At present, MUSTPAC™ has no specific capability to capture or visualize Doppler information in 3-D datasets, suitable for later reslicing.
- *No anatomic motion.* Conventional real-time 2-D ultrasound shows anatomic motion, such as pulsing arteries, as a moving image on screen. This is diagnostically useful. However, the 3-D scans captured by MUSTPAC™ are static snapshots. Generally speaking, anatomic motion produces image artifacts that the diagnostician must learn to recognize and ignore. In extreme cases, such as scanning an active fetus, anatomic movement can render a dataset unusable. This condition must be recognized by the scanner operator, and the scan repeated.
- *Static shadowing artifacts.* With conventional realtime ultrasound, the image is produced by insonification from the current transducer position, so shadow and posterior enhancement artifacts always look radial and shift location if the transducer moves. With MUSTPAC™, these artifacts are captured statically as they appeared during data acquisition. When the 3-D dataset is resliced on a different plane, shadows and enhancements can have an unusual appearance. Again, diagnosticians must learn to recognize and deal with these artifacts, typically by reviewing the data in the original plane of insonification to clarify the interpretation.
- *Data quality bounded by the original B-scans.* In the conventional clinical setting, skilled ultrasound technicians interactively adjust power, gain, TGC (time gain compensation), patient position, and other parameters to optimize images on a case-by-case basis. At present, the MUSTPAC™ system cannot make such adjustments by itself (since it has no direct control over the ultrasound machine), nor does it actively help the scanner operator to make them. Carefully chosen presets help to alleviate this problem. In the long run, we anticipate that automated image analysis will enable further improvements.

SUMMARY

3-D ultrasound data acquisition potentially can expand the use of ultrasound imaging in a telemedicine setting, by allowing an operator with no diagnostic skills to collect high quality scans that can be interpreted by a remote expert. This potential is illustrated by the MUSTPAC™ series of ultrasound telemedicine systems. Several prototype MUSTPAC™ systems have been developed and evaluated in a variety of operational environments. While the MUSTPAC™ approach is promising, significant further work remains before its clinical applicability is fully determined.

ACKNOWLEDGMENTS

Development and testing of MUSTPAC™ systems was funded by the Defense Advanced Research Projects Agency (DARPA) under contract number DAMD-17-94-C-4127. We are grateful to our program managers Dr. Rick Satava and Dr. Wally Smith for their support and guidance.

The Pacific Northwest National Laboratory is operated by Battelle Memorial Institute for the U.S. Department of Energy under Contract DE-AC06-76RLO 1831.

12 Broadax Systems Inc., El Monte, CA, http://www.bsicomputer.com

DISCLAIMERS

The opinions expressed in this article are those of the primary authors and do not necessarily reflect official policy of the United States Department of Defense, Department of Energy, Battelle, or Fraunhofer.

Reference to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the authors or their associated organizations.

MUSTPAC™ is a trademark of Battelle Memorial Institute. TeleInViVo™ is a trademark of Fraunhofer CRCG. All other trademarks are property of their respective owners.

REFERENCES

[1] Copel JA, Platt LD, Campbell S, "Prenatal ultrasound screening and perinatal outcome" (letter comment), New England Journal of Medicine 1994; **330**:571.

[2] Fisk N, Bower S, Sepulveda W, *et.al.*, "Fetal Telemedicine: interactive transfer of realtime ultrasound and video via ISDN for remote consultation", Journal of Telemedicine and Telecare 1995; **1**:38-44

[3] Fisk NM, Sepulveda W, Drysdale K, *et al.*, "Fetal telemedicine: six month pilot of real-time ultrasound and video consultation between the Isle of Wight and London", British Journal of Obstetrics and Gynaccology 1996; **103**:1092-5.

[4] Malone F, Nores J, Athanassiou A, *et al.*, "Validation of fetal telemedicine as a new obstetric imaging technique", American Journal of Obstetrics and Gynecology 1997; **177**:626-31.

[5] Macedonia CR, Littlefield RJ, Coleman J, *et al.*, "Three-dimensional ultrasonographic telepresence", Journal of Telemedicine and Telecare 1998; **4**:9803/3.1-7 (to appear).

[6] IEEE Engineering in Medicine and Biology Magazine, Theme Section titled "Advances in Ultrasound", V.15, No.6, Nov/Dec 1996: 18-101.

[7] Mayer JH, "Ultrasound marches to the front", Portable Design, June 1997:43-48.

[8] "Backpack remote medicine proves its worth", Jane's International Defense Review, Feb.1997, pg.15.

APPENDIX M

APPENDIX M: "*MUSTPAC™ 3-D Ultrasound Teleradiology / Telepresence System*", Project #30681 with Mercy Health System.

MUSTPAC™ 3-D Ultrasound Teleradiology/ Telepresence System

Project # 30681

Richard J. Littlefield
Laura M. Curtis
Heinz J. Roye
Lawrence E. Skelly

December 1998

Prepared for
Mercy Health System
One Bala Plaza, Suite 402
Bala Cynwyd, PA 19004

Information Sciences & Engineering Resources
Battelle Pacific Northwest Division
P.O. Box 999
Richland, Washington 99352

Contents

1.0 Summary

Problem Statement

Mercy Health System has proposed to the Department of Defense to conduct a study showing how the use of telemedicine devices will expedite the triage and treatment process in emergency situations for patients in remote areas, thereby improving timeliness, quality of care and patient outcomes. Data generated from this study will be compared to other telemedicine devices with the goal of establishing cost effective telemedicine devices for use in the remote and austere battlefield environment with technology transfer to the civilian at-home or assisted-living environments.

Mercy Health System proposes to include the MUSTPAC™ 3-D Ultrasound System in its study to determine if sonographic data acquired in volumetric fashion can be used by a physician at a site remote from where the data was obtained for a diagnosis with accuracy equal to that of the "gold standard" in-hospital real-time protocol.

Project Objective Statement

Deliver one MUSTPAC-3 prototype five months after contract award to Battelle Pacific Northwest Division (Battelle) for test and evaluation by Mercy Health System, and provide assistance for three months to Mercy Health System in performing that evaluation, for $372,609. MUSTPAC-3 will consist of engineering improvements that incorporate free-hand scan for gray scale into the MUSTPAC-2 system delivered under DOD Contract DAMD17-94-C-4127. Battelle also will pursue FDA 510(k) approval for the MUSTPAC-3 prototype using data resulting from the Mercy Health System study.

Project Benefits

Mercy Health System is a major provider of the medical and health services used by residents of Delaware County, Pennsylvania. The proposed collaborative research endeavor will generate data relative to the improvement in acceptance and delivery of telemedicine applications through the development of systems, policies, protocols, procedures, and educational products applicable to medical services management efforts both in the military and civilian health delivery sectors. Mercy Health System plans to use the MUSTPAC™ system as part of its state-of-the-art telemedicine network to improve the care provided in both emergency and non-emergency environments.

Mercy plans to conduct its study in two phases. Phase 1 will consist of an in-house clinical trial that will compare MUSTPAC-3 to the current "Gold Standard" ultrasound methodology. If Phase 1 successfully demonstrates the usefulness of the MUSTPAC system, then Phase 2 will take MUSTPAC-3 into the remote environment. Mercy will extend the use of the system to nursing homes, external health clinics and ambulance services. Data will be collected at the remote sites and transmitted to diagnostic experts centrally located in the major Mercy facilities for interpretation and analysis.

2.0 Deliverables

Deliverable	Description
MUSTPAC-3 Prototype, 1 each, to support Phase 1 of the Mercy study	MUSTPAC system with free-hand scan capability: • 3-D Free hand scanner device for data collection • Virtual Probe for data interpretation • Integrated MUSTPAC software
System Installation	Install MUSTPAC –3 Prototype on a Mercy computer and calibrate the system for use with a Mercy ultrasound instrument in a clinical environment
Monthly Project Status Report	Monthly status report

3.0 Scope

Execution of this project is dependent on support from two sponsors: Mercy Health System, Bala Cynwyd, Pennsylvania, and McKennan Medical System, Sioux Falls, South Dakota. The earlier versions of MUSTPAC™ were developed under a research project of the Defense Advanced Research Projects Agency (DARPA). DARPA's research objectives have been met and the project has moved into the technology transfer stage which is not being funded by DARPA. By jointly sponsoring the continuation of MUSTPAC research, Mercy Health System and McKennan Medical System will benefit, since they share a common desire to significantly improve the quality of healthcare provided to their patients through the application of emerging telemedicine systems like MUSTPAC™.

A single version of the MUSTPAC-3 prototype will be developed for both sponsors and delivered in the quantities specified in the individual project proposals of each sponsor. By sponsoring the continuation of the research each sponsor will receive an exclusive use license for its respective patient care region.

Battelle will deliver the MUSTPAC-3 software, the 3-D free hand scanner for data collection, the virtual probe for data analysis, and the computing platform to run these. Mercy Health System will provide the ultrasound instrument that will be used with the MUSTPAC-3 system. Battelle will calibrate the Mercy MUSTPAC system for use with the Mercy ultrasound instrument. Battelle also will provide user training concurrently with MUSTPAC installation and setup. A duplicate MUSTPAC-3 system will be placed at Battelle to support continued development and to serve as a "hot spare" in the event of equipment failure at Mercy.

Since MUSTPAC is an experimental medical device, it can be used only within the scope of a medical research protocol approved by appropriate IRBs (Institutional Review Boards). Mercy is responsible for preparing the protocol as well as submitting the protocol to the Mercy IRB. Federal regulations relating to Battelle's government contracts require that the protocol also be approved by the IRB at the Pacific Northwest National Laboratory (PNNL) in Richland, WA. Battelle will assist Mercy staff in the preparation of the protocol, to facilitate its acceptance by both IRBs. During the clinical trial Battelle will provide telephonic technical support to the Mercy staff.

Battelle will prepare and submit a device approval application to the U.S. Food and Drug Administration using the clinical trial data collected by Mercy and McKennan (FDA 510k application).

4.0 Background

Introduction

MUSTPAC™ is a family of ultrasound telemedicine systems based on the use of 3-D (volumetric) data acquisition. An operator with limited training and no ultrasound diagnostic skills, using a simple "point-and-shoot" procedure, can take diagnostically useful scans. For diagnosis, volumetric datasets are transmitted to a remote radiologist, who uses a "virtual ultrasound probe" to reslice the datasets along arbitrary planes, using familiar hand movements and seeing 2-D (planar) displays similar to those of a conventional real-time hands-on examination.

Health-care policy experts have become increasingly concerned about the uneven distribution of physicians. The lack of widespread availability of expertise in diagnostic ultrasound has been a particular problem. Recently, a number of groups have pioneered real-time remote ultrasound examination and have shown the value of tele-consultations for ultrasound technicians in rural areas.

However, conventional real-time 2-D (two-dimensional) ultrasound imaging has the significant drawback that a highly skilled operator must be physically present at the patient's location. This is because conventional 2-D ultrasound imaging uses a hands-on interactive procedure that requires the operator to make diagnostic decisions simply in order to position the image acquisition probe at the correct location and orientation.

For example, to allow a diagnosis of gallstones using conventional 2-D ultrasound, the operator must interactively manipulate the image acquisition probe to locate the gall bladder, image the bile duct at the correct angle to measure its diameter, and finally locate the stones within the bladder. A positioning error of only two or three millimeters, relative to the patient's internal anatomy, can make the difference between diagnostic images and useless ones. This need for precision pointing introduces some difficulties in using conventional 2-D ultrasound in a telemedicine setting, where the diagnostic expert does not have direct control over the probe positioning.

In contrast, using 3-D (three-dimensional) ultrasound potentially allows diagnostically useful scans to be taken by an operator with limited training, no diagnostic skills, and no real-time expert assistance. This is accomplished by having the system scan a fairly large volume of the subject's anatomy at one time, without interpretation, so that the operator can use a simple "point-and-shoot" strategy for data acquisition.

For example, to scan for gallstones using 3-D ultrasound, the operator has to know only enough anatomy to scan a volume that includes the gall bladder. Measuring the bile duct and locating individual stones is still required, but this analysis and diagnosis can be done later by an ultrasound expert located elsewhere.

System Overview

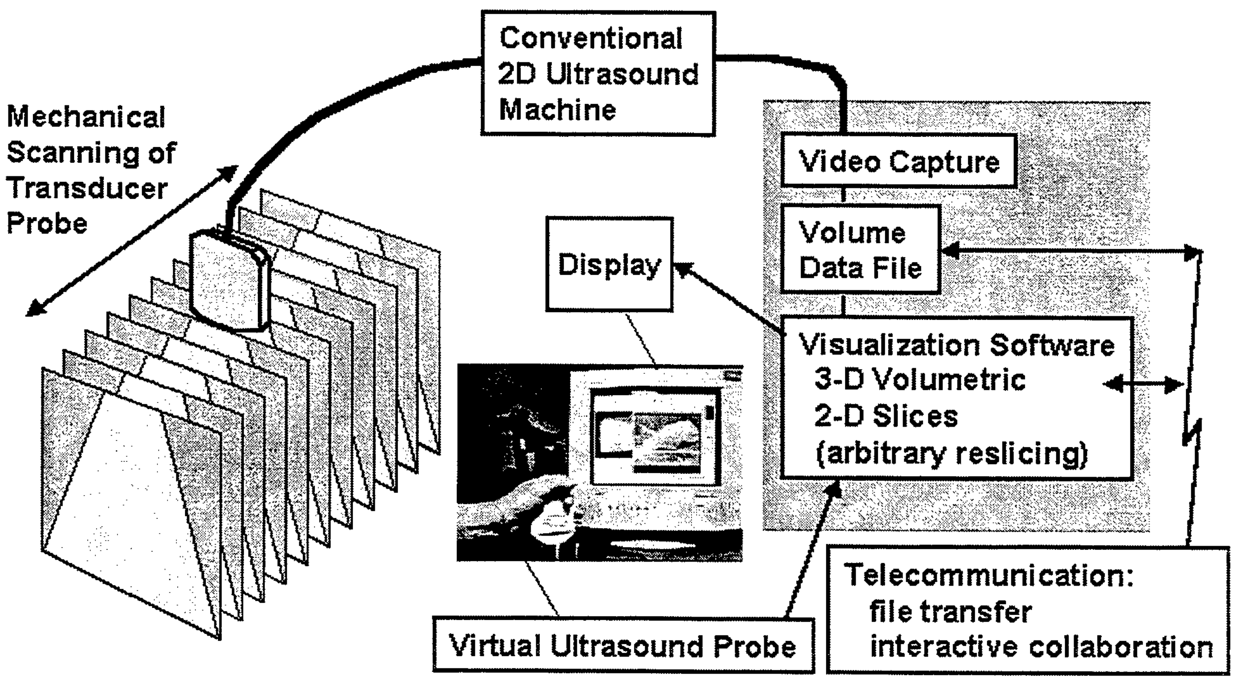
MUSTPAC™ is an ultrasound medical imaging system that can scan patients to generate 3-D volumetric digital datasets, interactively generate 3-D and 2-D images for use by diagnosticians, and optionally transfer datasets over standard communication links to facilitate remote diagnosis and consultation. It is

designed to work in a telemedicine framework, enabling diagnostically useful ultrasound scans to be taken by an operator with no diagnostic skills, modest training, and no online connection to an expert.

Typically a MUSTPAC™ system is used as follows. First, the patient is scanned by placing an ultrasound probe on the patient and mechanically sweeping it across his/her skin over the area of interest. During the scan, the system records ultrasound data from a sizable 3D volume of the patient's anatomy, producing a 3D volumetric data set of ultrasound reflectivity. The scanning process requires no interpretation of the ultrasound images, other than possibly to confirm that the intended anatomy is covered.

Scans in the form of 3D volumetric datasets are then transmitted over any standard digital network to a qualified diagnostician. Finally, a diagnostician interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2D slices from the 3D data set simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.

All versions of the MUSTPAC™ system developed to date have used a similar high level design. There are two primary operations — scanning and visualization — typically separated by a data transmission step.

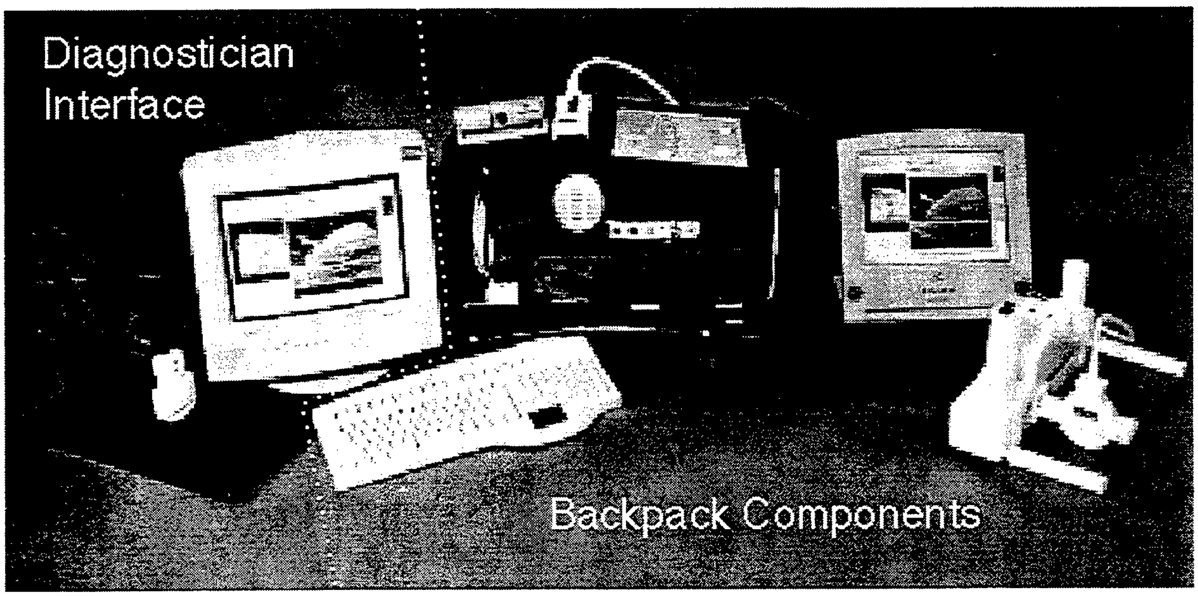


MUSTPAC-1

In the summer of 1996, the first prototype system was developed for testing by the U.S. Army under field conditions. This system, called the MUSTPAC-1, was designed to demonstrate an ultrasound telemedicine system in a backpack.

System components and packaging. Major components of the MUSTPAC-1 are shown below. These components include (right-to-left):

- Battery-powered linear scanner (at extreme right)
- Silicon Graphics Presenter™ flat panel display.
- Hitachi EUB-905™ ultrasound machine (in backpack, top section, with cord)
- Silicon Graphics Indy™ computer (in backpack bottom section)
- Teleconferencing camera (on backpack, top left)
- Keyboard with integral touchpad.
- High-resolution color monitor.
- Virtual Ultrasound Probe
- TeleInViVo™ visualization software.
- Other custom data acquisition and control software.



MUSTPAC-2

MUSTPAC-2 is actually a family of MUSTPAC™ systems implemented on a common base of Intel Pentium processors using the Windows/NT operating system. The principles of operation are similar to MUSTPAC-1. However, MUSTPAC-2 incorporates several significant improvements from the user's standpoint. These include:

- Simplified and more robust user interface
- Wider range of packaging options (e.g. lightweight and rugged data acquisition system versus high performance diagnostic workstation)
- Increased network compatibility.
- Faster transmission and reduced data volume (through JPEG data compression).
- DICOM v3.0 import/export capability.

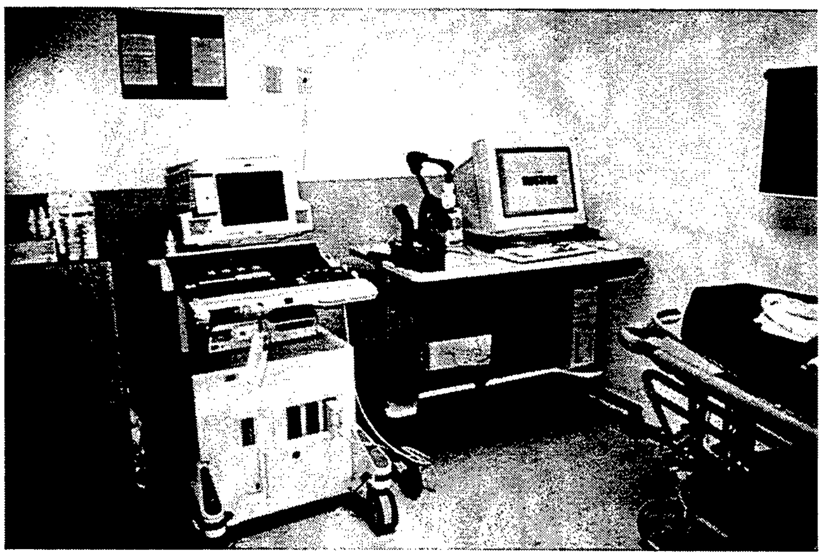
- Freehand scan (research quality– still under development for routine clinical use).

Several configurations of MUSTPAC-2 systems have been developed for specific purposes. These purposes include:

- Everest Extreme Expedition
- Hospital clinical evaluation
- Remote clinic consultation

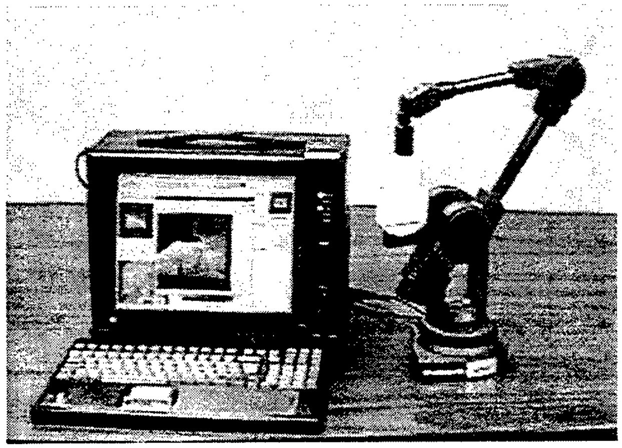
For the purposes of this proposal, two of the configurations will be further developed for delivery to Mercy Health System as MUSTPAC-3. They are the hospital and remote clinic versions.

Hospital clinical evaluation. A deskside system equipped for both scanning and visualization has been installed at the National Naval Medical Center (NNMC) in Bethesda, MD. This system is being evaluated for use in a clinical setting, prior to possible shipboard deployment.



This unit incorporates a 333 MHz Dell Dimension XPS computer (under desk), MUSTPAC-2 Virtual Ultrasound Probe based on the Microscribe 3D articulated arm (on table), MUSTPAC-2 linear scanner (on table), and NNMC's existing ATL HDI-3000 ultrasound machine (console and cabinet at left).

Remote clinic consultation. The "lunchbox" configuration focuses on data acquisition, with limited capability for visualization. This demonstration/evaluation unit represents a configuration being considered for installation in a network of telemedicine clinics in rural northern U.S.



This portable "lunchbox" configuration incorporates a 200 MHz BSI LCD V8 computer, MUSTPAC-2 linear scanner (not shown), MUSTPAC-2 Virtual Ultrasound Probe, and any of several existing ultrasound machines (also not shown).

5.0 Technical Approach

As outlined above, current MUSTPAC-2 systems (like the one installed at NNMC) are based on the use of a motor-driven linear scanning device, TeleInViVo™ visualization software, and communication protocols used at sites where installations have been done to date. These features are not sufficient to meet the requirements of Mercy Hospital's intended usage of MUSTPAC.

To support Mercy Hospital, Battelle proposes to extend and refine MUSTPAC-2, thereby producing a next-generation system called MUSTPAC-3, and to specialize MUSTPAC-3 for Mercy Hospital's operational environment.

In particular, from the standpoint of delivered functionality, Battelle proposes to:

- Replace the motor-driven linear scanning device with a free-hand scanning capability, where the ultrasound probe is hand-held and its position and orientation are sensed instead of controlled. This will allow the ultrasound probe to follow body contours and be tilted to scan around obstructions (such as looking upward under the rib cage). It will also allow performing scans in many special situations, such as collecting images for cervical length measurements by using a vaginal probe with a side-to-side tilting/sweeping movement.
- Implement the free-hand scanning capability using state-of-the-art electro-optical and mechanical technology that is highly accurate and reliable even in the presence of metal, variable magnetic fields, etc.
- Extend the range of measurements provided by the visualization software to include angles and volumes, and to view the original (non-parallel) freehand scan images, in addition to the arbitrary reslicing that is currently provided.
- Provide file conversion and communication software as needed to make MUSTPAC-3 interoperate with Mercy Hospital's existing system for radiology image storage and retrieval.

The following actions are planned to provide the above functionality:

- Replace the current visualization software (TeleInViVo™) with a different software package (3D FreeScan™) that integrates free-hand scanning capability and visualization.
- Utilize the MicroScribe™ high resolution mechanical arm as a 6-D spatial positioning input device for both data acquisition (scanning) and visualization (reslicing, using the virtual probe). There are two major parts to this work:
  - Extend the 3D FreeScan™ software to support the MicroScribe™ arm.
  - Design and fabricate mechanical mounting devices to attach real and virtual ultrasound probes to the MicroScribe™ arm, and to hold the arm in comfortable positions for clinical use.
- Extend MUSTPAC™ communication hardware and software as needed to operate in the Mercy Hospital environment.
- Extend MUSTPAC™ file conversion software for compatibility with Mercy Hospital's image storage and retrieval system.
- Procure hardware and software licenses for MUSTPAC™ installation at Mercy Hospital and a development / hot spare system at Battelle, including two each computer systems, MicroScribe™ arms, video capture cards, FreeScan™ licenses, digital cameras, communication interfaces, and routinely required commercial utility software such as Microsoft Office, disk defragmenter, WSFTP, PKZIP.
- Develop new end-user training and documentation materials covering Mercy Hospital's targeted applications for MUSTPAC™.
- Visit Mercy Hospital to install MUSTPAC™ equipment, calibrate the MUSTPAC™ system for use with the ultrasound system to be provided by Mercy Hospital, and train Mercy personnel on MUSTPAC™ use.

6.0 Task Descriptions/Statement of Work

Task 1. Develop free-hand gray scale scan capability for the MUSTPAC system that enables the collection of diagnostically useful ultrasound data by an operator with limited training and no ultrasound diagnostic skills, using a simple "point and shoot" procedure.

Task 2. Develop the software to support: calibration of the MUSTPAC-3 for use with the Mercy ultrasound instrument; interface of the MUSTPAC-3 with the Mercy computer network, the Mercy PACS, and the DICOM standard in use.

Task 3. Install free-hand scan prototype on the Mercy computing platform. Installation will include a free-hand scanner, a diagnostic virtual probe and the MUSTPAC-3 software. The installation will be calibrated to the ultrasound instrument provided by Mercy. Network communications interface, PACS and DICOM support and data compression will be confirmed during the installation. Document the setup. Provide user training during the MUSTPAC-3 installation. Provide telephonic "help" support for 90 days after the installation.

7.0 Schedule

Milestone	Date
Task 1. Complete MUSTPAC-3 prototype free-hand scan development	5 months after award of contract
Task 2. Complete software development to support MUSTPAC-3 installation at Mercy facility	4 months after award of contract
Task 3. Install MUSTPAC-3 prototype at Mercy facility	Within 30 days after completion of Task 1
Monthly Project Report	By 10^{th} of each month

8.0 Budget

[deleted from project DAMD17-94-C-4127 report]

APPENDIX N

APPENDIX N: ***"MUSTPAC™ 3-D Ultrasound Telemedicine Imaging System", flyer distributed at the DOE Biomedical Technologies Exposition, Washington DC.***

Distribution

No. of Copies	Offsite
3	U.S. Army Medical Research and Medical Command (MRMC)
1	Richard M. Satava, MD.
3	Wallace A. Smith, Ph.D.
1	Michael Goldblatt, Ph.D.
1	Robert Carnes, MD.
1	Christian R. Macedonia, MD.

No. of Copies	Onsite
12	RJ Littlefield
1	SE Davis-Cross
1	BA Garrett
1	TS Tenforde
1	LMS Curtis
1	RA Kennedy
1	JD McCall
1	C Winters
1	LE Skelly
1	SR Doctor
1	KA Cook
1	JJ Thomas
1	RW Quadrel
3	TJ Doherty
1	HD Collins
1	WM Lechelt
1	DM Sheen